GUIDANCE FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

CHLORDIMEFORM OR CHLORDIMEFORM HYDROCHLORIDE

AS ACTIVE INGREDIENTS

059701

AND

059702

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

CASE NUMBER 0141

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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 generally 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 provide additional data to support existing registration, 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 unreasonable adverse effects on the environment. The Registration Standard may lead to initiation of a Special Review if it appears that use of the product may cause unreasonable adverse effects on the environment. The Special Review can result in a decision by the Agency to seek a change in the conditions of registration, suspension, or cancellation of the registration.

The scientific review, which is not contained in this Guidance Package but is available from the National Technical Information Service, focuses 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 regarding the hazards which 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 does not currently qualify but 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 may 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 a 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 manufacturing-use products containing the pesticides chlordimeform or chlordimeform hydrochloride as sole active ingredients. The Agency bases its position and rationale on a consideration of all uses of chlordimeform and chlordimeform hydrochloride appearing on pesticide products registered under sections 3 and 24(c) of the FIFRA as well as on products authorized for distribution in intrastate commerce under 40 CFR 162.17. Both active ingredients are included in this one Guidance Document, rather than in separate documents, because of their close chemical association as well as the similarity of their data bases and use pattern. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of these pesticides and their 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 chlordimeform and chlordimeform hydrochloride manufacturing-use products (MPs) in order for their products to be registered or reregistered under this Guidance Document. Unique labeling requirements and certain data needs for end-use products (EPs) containing either of these active ingredients are also established by this Guidance Document. 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 Guidance Document may be subject to additional data and/or labeling requirements.

B. Description of Chemical and Use Profile

"Chlordimeform" is the official common name given by the American National Standards Institute (ANSI), the International Standards Organization (ISO) and the British Standards Institute (BSI), for the basic form. Chlordimeform hydrochloride (HCl) is the name for the hydrochloride salt form. The nomenclature designations in Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels (U.S. EPA, 4th edition, December 1979) are as follows:

Chlordimeform (ANSI) = N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidine

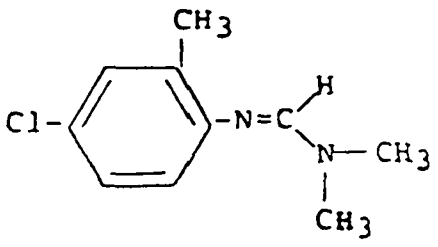
Chlordimeform hydrochloride (ANSI) = N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidine hydrochloride

Other identifying information and names are as follows:

Chlordimeform:

Molecular formula: $C_{10}H_{13}ClN_2$
Molecular weight: 196.67
Elemental Composition: C-61.0[illegible], H-6.66%
Cl-18 , N-14.24%
Pesticide Chemical Code No.: 059701
Chemical Abstracts Service (CAS) Registry No.: 6164-98-3

Structural Formula:

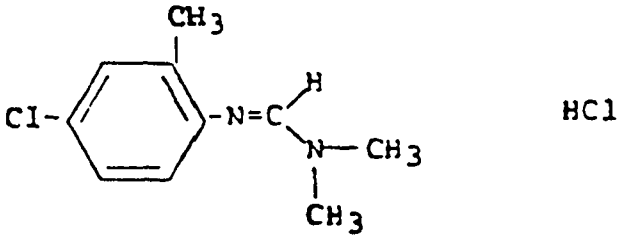


Other names are: N'-(4-chloro-2-methylphenyl)-N,N-dimethyl-methanimidamide, N'-(4-chloro-o-tolyl)-N,N-dimethylformamidine, N,N-dimethyl-N'-(2-methyl-4-chlorophenyl)-formamidine, Acaron (Schering AG, discontinued), Bermat®, chlorfenamidine, chlorophenamidin, chlorophenamidine, chlorophenamidine (ISO, withdrawn), C 8514, Ciba-8514, ENT-27335, EP-333, Fundal® 500, Fundex® (Schering AG discontinued), Galecron®, RS 141, Schering 36,268, SN 36268 (Schering AG), Spanon (Nichino;Japan), Spanone® (Schering AG discontinued), and Spike (Australia).

Chlordimeform hydrochloride:

Molecular formula: $C_{10}H_{13}ClN_2 \cdot HCl$
Molecular weight: 233.13
Pesticide Chemical Code No.: 059702
Chemical Abstracts Service (CAS) Registry No.: 19750-95-9

Structural formula:



Other names are: N'-(4-chloro-2-methylphenyl)-N,N-dimethyl-methanimidamide monohydrochloride, N'-(4-chloro-o-tolyl)-N, N-dimethylformamidine monohydrochloride chlorophenamidine hydrochloride, ENT-27567, EP-333, Fundal® S Galecron® SP, and Spanone®.

Chlordimeform is a medium strength base which forms crystalline salts with strong acids, such as hydrochloric acid. Technical chlordimeform is a liquid to partly crystalline solid and is pale yellow to brown in color. The melting point is 35°C and its boiling

point is 163°C for the pure active ingredient. It readily dissolves in organic solvents and hydrolyzes in neutral or alkaline solutions to form N-formyl-4-chloro-o-toluidine and then to 4-chloro-o-toluidine.

Technical chlordimeform HCl is a crystalline powder of white to tan color. The melting point is 225 to 227°C with decomposition for the pure active ingredient. Chlordimeform HCl is highly soluble in water.

Chlordimeform and chlordimeform HCl are manufactured in the United States by Ciba-Geigy Corporation and Nor-Am Agricultural Products, Inc. Both companies also produce end-use products, as does FMC Corporation. There are a total of six products currently registered which contain chlordimeform as the active ingredient and five products which contain the hydrochloride. Ciba-Geigy has two technical products, a 95 percent chlordimeform and a 95 percent chlordimeform HCl, and two end-use products. These are Galecron® 4E (48.5% ai) and Galecron SP (95% ai).

Nor-Am has two technicals, a 97 percent chlordimeform, a 97 percent chlordimeform HCl, a 90 percent chlordimeform manufacturing intermediate product, and two end-use products. The EP are Fundal® 4EC (48.5% ai) and Fundal SP (soluble powder) (97% ai). FMC has two EPs which are Fundal 4 EC (48.5% ai) and Fundal® SP (97% ai). There are two Special Local Need (section 24(c)) products and 16 intrastate products.

Chlordimeform and chlordimeform HCl are currently registered for use on cotton as insecticides and acaracides and as yield enhancers. Both pesticides are classified as Restricted-Use which permit sale and use only by certified applicators or someone under their direct supervision.

C. Regulatory Background

Chlordimeform and chlordimeform HCl were first registered in 1968 for use on apples. Between 1968 and 1976 the following additional crops were registered: cotton, pears, cherries, nectarines, peaches, plums (fresh prunes), broccoli, brussels sprouts, cabbage, cauliflower, tomatoes, walnuts, seed alfalfa and clover. These pesticides' major use was on cotton as ovicides and larvicides against the bollworm and tobacco budworm. In 1976, all crops but cotton were voluntarily withdrawn by the registrants for the reasons discussed below. In 1982 the claim that chlordimeform and chlordimeform HCl perform as cotton yield enhancers was added to EP labels.

Before 1976, data from rat and dog studies had been generated to support the chronic toxicology requirements of these pesticides and their crop tolerances. None of these data demonstrated carcinogenic effects. However, in 1976 Ciba-Geigy notified the Agency that it was going to voluntarily initiate an immediate halt to production, a stop sale and a recall of its products because preliminary results of a chronic mouse toxicology study suggested that chlordimeform was causing malignant tumors

(hemangioendothelioma--tumor of the liver blood vessels). The other registrants took similar action with their products. Before the recall took effect in 1976, Ciba-Geigy monitored workers in production and formulating plants. Chlordimeform and its metabolites were found in plant workers' urine at levels of 2 to 40 parts per million.

Between the cessation of production in 1976 and 1978, the companies developed a plan to reintroduce the pesticides for the use on cotton only. The plan was to minimize exposure to all workers involved with the mixing, loading and application of the pesticides to cotton. New use restrictions included: 1) retain the cotton use only and voluntarily cancel all others; 2) require the use of protective clothing; 3) use closed systems for mixing and loading; 4) limit application by air only; 5) prohibit the use of flagmen; 6) reduce the maximum application rate on cotton from 1.0 to 0.25 lb active ingredient per acre (a.i./A); 7) initiate a training and exposure monitoring program for mixers, loaders and applicators; and 8) label products with a 1-day reentry restriction. Closed systems are equipment systems for pesticide storage, transfer, mixing loading and application which have appropriate connections, meters, pumps and plumbing designed to minimize (ideally, eliminate) human exposure. Additionally, the Agency imposed the restricted use classification for all EP products; this classification requires applicators either to be "certified" or to work under the direct supervision of a "certified applicator". In accepting

the companies' plan as amended by EPA, the Agency believed that implementation of these use restrictions would significantly reduce the exposure to those involved in applying the products and still provide pest control for cotton growers. With these modifications, products were reintroduced in 1978. In 1982, Ciba-Geigy proposed a cancer statement for its products. The Agency accepted the proposal and imposed a cancer statement for all products.

D. Current Science Assessment

Toxicology

Oncogenicity

Since 1969 the Agency has received and reviewed 11 chronic feeding and oncogenicity studies of chlordimeform and chlordimeform HCl and the metabolites N-formyl-4-chloro-o-toluidine, 4-chlor-o-toluidine HCl and 4-chloro-o-toluidine in the mouse and rat. Five of these studies were conducted with the mouse and six with the rat. Most of these 11 studies were conducted during the 1970's and submitted to and originally reviewed by the Agency between 1978 and 1981.

The Agency's assessment of these studies reveals that certain studies are more adequate than others for current testing standards. Flaws or inadequacies in certain studies include such problems as a lack in reported detail of methods and results, incomplete raw data records, and incomplete histopathological examination. However, because of the unusually high number of chronic studies and the fact that there is a variety of test materials/test species and strains combinations (i.e., technical pesticide compounds and

metabolites tested on different animal species and strains), it is the Agency's opinion that the full composite of the data is sufficient to adequately characterize the chronic toxicity and to satisfy the data requirements.

Five chronic feeding studies were performed in mice. Chlordimeform HCL, 4-chloro-o-toluidine, and N-formyl-4-chloro-o-toluidine were each studied once, and 4-chloro-o-toluidine HCL was studied twice. Four of these studies were considered adequate and they each demonstrated significant dose-related increases in tumor rates in male and female mice. The fifth study, an 80-week study of 4-chloro-o-toluidine, was considered inadequate for a variety of reasons including: non-treatment related disease in the test animals, decomposition of tissues, and failure to collect or report data.

Of the four studies which were adequately conducted, three are particularly useful; the fourth was givin less weight than the other three for the purposes of this document because it was a bioassay which was conducted with extremely high dose levels.

In the chlordimeform HCl study, there was a significant increase in the numbers of hemangioendotheliomas and hemangiomas in male and female mice at the higher dosage levels of 100 and 500 ppm. The lowest effect level (LEL) was 100 ppm and the no observable effect level (NOEL) was 20 ppm. In one of the 4-chloro-o-toluidine HCl studies, hemangioendotheliomas and hemangiomas were produced in significant numbers in both sexes at the upper three dosage levels of 20, 100 and 500 ppm; the LEL was 20 ppm and the NOEL was 2 ppm. In the other 4-chloro-o-toluidine HCl study, an NCI bioassay with

very high dosage levels, hemangiosarcomas and hemangiomas were produced at 1250 (lowest dose tested (LDT)) in females and at 15,000 ppm (HDT) in males; the NOEL for males was 3750 ppm. In the fourth mouse study, N-formyl-4-chloro-o-toluidine was positive for hemangioendothelioma and hemangiomas at the upper dosage levels of 100 and 500 ppm. The LEL was 100 ppm and the NOEL was 20 ppm.

There are six chronic feeding/oncogenicity rat studies that have been submitted and reviewed by the Agency. Chlordimeform and chlordimeform HCl and the metabolites 4-chloro-o-toluidine and N-formyl-4-chloro-o-toluidine were each tested once and 4-chloro-o-toluidine HCl was tested twice in the oncogenic studies. Chlordimeform was tested at dose levels of 100, 250 and 500 ppm in the rat's diet with no evidence of treatment related oncogenicity. Chlordimeform HCl was tested at levels of 2, 20, 100 and 500 ppm in the diet and was negative for oncogenicity. In the 4-chloro-o-toluidine study, dose levels of 20, 100 and 500 ppm were tested. At the highest dose level, there was a slight increase in tumor (hepatoma) incidence compared to the control and the other treatment groups. However, due to the lack of proper neoplasm characterization, it is difficult to make a definitive conclusion about oncogenicity in this study. NCI bioassayed 4-chloro-o-toluidine HCl at levels of 1250 and 5000 ppm for which there were no treatment related increase in tumors. In the other 4-chloro-o-toluidine HCl study, in which the dose levels were 2, 20, 100 and 500 ppm, the Agency concluded it was not oncogenic at the levels tested. In the sixth oncogenic study, with the N-formyl metabolite, dose levels of 2, 20, 100 and 500 ppm were tested. At the highest dose level, there was an increase in

benign cholangiomas. However, because the non-neoplastic histopathology data are missing from the study, the Agency concludes that it is inadequate to characterize the oncogenic effects. The Agency believes that these rat studies do not clearly demonstrate that the parent compounds or their metabolites are oncogenic in the rat.

The Agency's review of the oncogenicity data has resulted in the classification of chlordimeform and chlordimeform HCl as "probable human carcinogens". This classification is based on the weight of evidence from positive studies with multiple strains in one species of test animal (mouse) and a dose related increase in the rate of malignant tumors in that species. Additionally, the mutagenicity findings, discussed below, support the carcinogenicity evidence. This classification is based on the Agency's published Proposed Guidelines for Carcinogen Risk Assessment (FR, 11/23/84). The weight of evidence presented here falls into the group "B2," or "probable human carcinogen."

The statistical evaluation of the data from the mouse studies resulted in multiple potencies of carcinogenicity ranging from 0.5 to 19.2 $(mg/kg/day)^{-1}$, depending upon the compound (parent or metabolites) tested, sex of mouse, duration of the study and statistical model. However, the calculated higher potency values (6.5, 12.0, 12.9 and 19.2 $(mg/kg/day)^{-1}$) are not considered as meaningful for risk assessment purposes as the other values because 1) the control animals were not sacrificed until up to 7 1/2 months after the higher dose animals were sacrificed, 2) because of this additional life span, the older animals developed tumors and

3) these circumstances skew the statistical analysis of these data which result in artificially high potency values. A potency value of 1.0 $(mg/kg/day)^{-1}$, which approximates the most common of the calculated values, was chosen to be used for the risk assessments, which are presented below in section C., Risk Assessment.

Mutagenicity

The Agency has 20 mutagenicity studies on the technical and metabolite compounds. From the ten studies with chlordimeform and chlordimeform HCl, the data do not demonstrate mutagenicity. However, the data from 10 other studies on metabolites, including desmethyl chlordimeform (1 study), N-formyl-4-chloro-o-toluidine (3 studies), 4-chloro-o-toluidine (3 studies), 4-chloro-o-toluidine HCl (1 study), 5-chloro-2-toluidine (1 study), and 4-4'-dichloro-2-2'-dimethyl-azobenzene (1 study) do demonstrate mutagenic effects. The desmethyl metabolite study suggests a slight increase in the rate of base substitution mutations in Salmonella typhimurium. One of the three N-formyl metabolite studies produced a back mutation in the same test species. The other two studies were not positive for mutagenic effects. In two of the three 4-chloro-o-toluidine study, positive mut· enic effects (base substitution in the above test species) were seen. In the other 4-chloro-o-toluidine study, which was a mouse spot study, there was increased incidence of color spots (genetic alteration). 4-chloro-o-toluidine HCl produced back mutations in S. typhimurium. Both the 5-chloro-2-toluidine and 4-4'-dichloro-2-2'-dimethyl azobenzene metabolites were negative for mutagenic effects in S. typhimurium. These

mutagenicity data suggest a correlation with the oncogenicity data. The positive mutagenic effects occurred with the metabolites that produced positive oncogenic effects in the mouse.

Other Chronic Effects

The effects seen in chronic rat studies with chlordimeform were similar to those seen in a chronic dog study. There was reduced food intake and growth in males and females at a dietary level as low as 400 ppm (rat). Methemoglobin formation in female rats occurred at 20 ppm. Erythrocyte and leukocyte counts, hematocrit, hemoglobin and serum albumin were decreased as were spleen and kidney weights (dog). There were also nodules and focal hyperplasia of hepatocytes and bile duct hyperplasia. The NOELs were 2 ppm (LDT) in the rat and 250 ppm (LDT) in the dog.

Teratology and Reproduction

Chlordimeform has been tested in two rabbit and one rat teratology studies and it was not teratogenic at the highest dosages tested--100 mg/kg (rabbit) and 50 mg/kg (rat). Parental mortality, abortion rate, ratio of implantations to the corpus lutea, the average number of pups per litter, incidence of resorptions, fetal weight and length and the incidence of skeletal and soft tissue anomalies were not affected. A 3-generation rat reproduction study with

chlordimeform did not result in any adverse reproduction effects. At the highest dose tested, 500 ppm, there was a reduced lactation index and weight of the weanlings. However, the fertility, gestation and live birth indices, sex ratio, the average number of pups per litter and birth weight were normal. The fetal NOEL was 250 ppm. This study was deficient however in detail reported and therefore it must be upgraded by the submission of this missing detail.

Metabolism

Many of the animal and plant metabolites have not been identified. However, from the available metabolism data it appears that the metabolic pathways in animals and plants (cotton) are similar and result in some of the same metabolites. Certain of these metabolites (4-chloro-o-toluidine and N-formyl-chloro-o-toluidine) are carcinogenic, as discussed above. 4-chloro-o-toluidine has been found in human urine following the handling and application of chlordimeform.

Metabolism studies in the rat, mouse, dog and goat show similar qualitative characteristics. After oral dosing, chlordimeform is quickly absorbed, metabolized and excreted. Within two to three days, between 70 to 95% of the parent and metabolites are excreted in the urine and feces. The remaining amounts are incorporated into tissues (primarily the liver and kidney).

Acute Toxicity

Chlordimeform and chlordimeform HCl are of moderate acute toxicity. Oral LD_{50}'s in the rat and dog range from 140 to 406 mg/kg, respectively. Acute dermal toxicity is moderate with a LD_{50} (rabbit) greater than 4000 mg/kg, mild skin irritation and no sensitization. Chlordimeform does cause mild eye irritation. Human toxicity effects include skin rash, abdominal pain, dysuria, urgency to void, hematuria and hemorrhagic cystitis. These effects were experienced in nine of 22 exposed workers in 1975 at a chlordimeform formulation plant, in which it is thought that these workers were exposed to abnormally high levels of chlordimeform.

Exposure

Pesticide Applicator Exposure

As part of this Registration Standard review, the Agency reviewed exposure data collected by Ciba-Geigy in 1976 and 1977, by Ciba-Geigy and Nor-Am from 1978 to 1981 under the terms of the reintroduction program and by the California Department of Food and Agriculture. Most of these monitoring studies only report the metabolite residues in the urine of workers associated with the pesticides' applications to cotton. Urine metabolite monitoring, rather than dermal exposure sampling, was used as a means to monitor individual worker exposure to these pesticides. Daily monitoring was used to determine whether or not an individual's exposure had reached a threshold level and he would have to refrain from work until his residue level dropped to an acceptable level. This

monitoring was not intended to measure dermal exposure. These data are difficult to compare and evaluate because: 1) they are in summary form, 2) they are reported in different formats and presentations, and 3) total daily urine output for individual workers, total potential worker exposure (dermal and inhalation) and time and location relationships of exposures to urine samples are unreported. More specifically, urine samples were collected after the time period which is expected to have maximum residues; there is difficulty in relating urine residue levels to total dermal/body exposure; data are of pooled values rather than individual, raw data; and, in the case of a dermal exposure study, there are too few replicates. The Agency is requiring that these deficiencies be corrected. Even though these deficiencies exist, these data provide substantial insight to actual exposure levels through their logical and consistent results. Because these studies appear to be meaningful despite their deficiencies, they are discussed below.

Between 1978 and 1981 extensive worker exposure monitoring studies were performed by Ciba-Geigy and Nor-Am. Urine metabolite data were collected from workers involved with chlordimeform spray programs on cotton and in which the reintroduction use restrictions (including protective clothing) were used. With these restrictions, the distribution of average daily exposures was as follows: 51 percent of the workers were below the 0.05 ppm level of detection; 33 percent were between 0.05 and 0.29 ppm; 10 percent were between 0.30 and 0.99 ppm; and, 5 percent were 1.00 ppm or greater. This

distribution was approximately the same for workers in the southeast U.S., south high plains of Texas, and Mississippi delta cotton areas, although the product is used primarily in the Mississippi delta.

Of the worker categories, pesticide loaders and maintenance workers had the highest exposures and site management personnel had the lowest. Based on these data, the Agency's calculated weighted average for a daily level of metabolites in the workers' urine samples is 0.1 ppm.

In 1976 and 1977, Ciba-Geigy conducted studies to compare worker exposure to chlordimeform from the use of extensive protective measures versus little or no protective measures. At the time of the voluntary suspension, the only required worker protection measure was the use of goggles when handling. The extensive protective measures were those later proposed and adopted for the reintroduction program. Exposure was measured by total chlordimeform metabolites in urine. Without the protection measures, 40% of the workers had between 0.05 and 0.29 ppm of metabolites in the urine, 10% had between 0.30 and 0.99 ppm and 50% had 1.0 ppm or greater. With the extensive protectionary measures, 60% of the workers had between 0.05 and 0.29 ppm, 20% had between 0.30 and 0.99 ppm and 20% had 1.0 ppm or greater. Also, in the study with protective measures 60% more active ingredient was applied per day. Correcting for the greater amount of applied active ingredient that workers may have been exposed to, there is a 3.6 fold decrease in exposure from the use of protective clothing and equipment.

In conducting a preliminary exposure assessment of these data, the Agency also compared data it has received from other sources because of the difficulties the Agency has with interpretation of the Ciba-Geigy/Nor-Am data. In 1982 and 1983, the California Department of Food and Agriculture (CDFA) conducted two exposure studies of chlordimeform and chlordimeform HCl for the cotton use. Potential inhalation and dermal exposure to pilots, mixers/loaders and flaggers was monitored. Aerial applications of soluble powder and emulsifiable concentrate formulations were made. Protective clothing was worn as required by the product labels. Standard patch techniques were used to measure dermal exposure to protected and unprotected areas of the body. Average dermal exposure values for the two studies were: pilots--40 ug/hr, mixer/loaders -- 34 ug/hr, and flaggers -- 35 ug/hr. No inhalation residues were detected. The number of replicates in both studies was low, which limits the utility of the data and results. The CDFA study notes that dermal exposures of mixer/loaders might have been lower because of extraordinary care taken in handling, mixing and loading due to the workers' knowledge of the monitoring and the presence of observers.

Also, the Agency compared results from a recent exposure study conducted by the British Agrochemicals Association, Limited (BAAL). BAAL monitored the exposure of protective clothing articles of mixers/loaders to emulsifiable concentrate formulations of other pesticides. The results were used to model exposure of the pesticide to unprotected areas. The data were collected in terms of the amount of exposure per work task rather than by time. However,

after making adjustments for the time required for each task and for the efficacy of specific articles of protective clothing, these exposure measurements provide estimates for comparison of exposure with and without certain protective clothing. This is presented in more detail in footnote 3 of the table below.

The Agency compared the results of the CDFA studies with its dermal exposure data base for surrogate pesticides and with studies conducted by BAAL with surrogate pesticides. The comparative yearly dermal exposure values for different worker categories is presented below.

YEARLY EXPOSURE VALUES (mg/kg/year)

Worker Category	EPA Data Base[1]	CDFA Studies[2]	BAAL Studies[3]
Mixers/ Loaders	10.3	0.03	8.3
Pilots	0.2	0.1	-
Flaggers	0.6	0.002	-

[1] Studies were performed since 1979 with pesticides other than chlordimeform but with similar formulations. Two studies were used for the mixers/loaders exposure that used closed systems and gloves for the workers. The flagger exposure was reduced by 90% due to protective clothing requirements of the label.

Studies conducted with very limited number of replicates using both the SP and the EC formulations. The protective clothing was worn as per label instructions.

[3] This study measured mixer/loader exposure with EC formulations and provided dermal exposure values assuming no protective clothing. The exposure value assumes 90% of the dermal exposure to the hands and the use of neoprene gloves which provides a 90% reduction in hand exposure. Rain suits and aprons were assumed to reduce body exposure (other than hands) by 80%. The use of a closed system was assumed to reduce total dermal exposure by 90%.

At this time, the Agency believes that the exposure values from its surrogate pesticide data base and the BAAL study are more accurate and representative of actual chlordimeform exposure than the Ciba-Geigy, Nor-Am or CDFA studies. As discussed above, the companies' data have serious deficiencies and flaws that prevent the Agency from making reliable and accurate estimates of whole body exposure. Also, as stated above, the CDFA studies have only a limited number of replicates which diminishes the reliability of the results. If the two companies' data can be upgraded so that the Agency can make reasonably accurate conversions from the urine metabolite data to total body exposure values, then the Agency will consider these data for exposure assessments.

Aside from the reported incident of chlordimeform formulation plant workers which were effected, as mentioned above, the Agency is not aware of any other incident or accident history with these pesticides. There are no reported human poisoning cases in the Agency's Pesticide Incident Monitoring System.

Dietary Exposure

Dietary exposure to chlordimeform and its metabolites results from consuming cotton seed oil and meal, meat, poultry, eggs, and milk and other dairy products containing residues of these compounds. The established tolerances for these commodities range from 5.0 ppm for the cotton seed oil to 0.25 ppm for the meat and poultry and 0.05 ppm for the eggs, milk and other dairy products. However, available data suggest that realistically, the residue levels and intake are more likely to be much lower than the tolerance levels

(level of detection is 0.05 ppm). Historically, not more than 10% of all cotton acreage is treated with either chlordimeform or chlordimeform HCl annually. Further, the available residue data suggest that the real residues are one to two orders of magnitude lower than many of the tolerances. For example, studies in food producing animals have shown detectable residues in only liver and kidney (about 0.1 ppm), not in muscle, poultry, fat, milk and eggs which comprise most of the dietary intake for chlordimeform containing commodities. With the use of these more realistic residue levels the estimated dietary exposure is about 0.0006 mg/kg/day for the average adult.

Risk Assessment

Workers

In a preliminary carcinogenicity risk assessment of workers, the Agency used the dermal exposure values presented above in the Yearly Exposure Values table. The resulting risk values are as follows:

ESTIMATED RISKS FOR WORKERS[1]

Worker Category	Agency Data Base	CDFA Studies	BAAL Studies
Mixers/ Loaders	4×10^{-3}	1×10^{-5}	3×10^{-3}
Pilots	8×10^{-5}	4×10^{-5}	-
Flaggers	2×10^{-4}	8×10^{-7}	-

[1] These values are for the upper 95% level for a B2 oncogen classification. They also reflect an estimated life expectancy of 70 years and 35 years working lifetime. The potency factor for chlordimeform is assumed to be 1.0. Dermal penetration is assumed to be 30% according to preliminary human studies.

Dietary

Dietary exposure from residues in cottonseed oil and in meat, milk and eggs from animals consuming cottonseed hulls, results in the upper bound 95% level of calculated carcinogenicity risk values from 1 x 10^{-4} to 10^{-7} depending upon residue levels assumed and the percent of the cotton crop which is assumed to have been treated with chlordimeform and chlordimeform hydrochloride. The 10^{-4} risk level assumes that residues are at the level of detection and that 100 percent of the crop is treated, which is an assumption the Agency traditionally makes in initial risk assessments. Historically, between 5 and 10 percent of cotton has been treated with these active ingredients. Using this estimate and more reasonable expected residue levels, the dietary risk value is about 10^{-6} or less. However, both the worker and dietary risks may be underestimated because current analytical chemistry methods are not adequate in detecting or quantifying all metabolites which may be of toxicological concern in plant and animal tissues.

Environmental Fate

The available environmental fate data are inadequate to fully characterize the fate of chlordimeform and chlordimeform HCl in the environment. However, the available data do suggest the following characteristics.

Chlordimeform hydrolyzes at a faster rate with increased pH and temperature with N-formyl-4-chloro-o-toluidine being the major hydrolysis product. Under aerobic conditions chlordimeform and chlordimeform HCl rapidly dissipate in loam, sandy loam, silt loam and clay loam soils with half-lives of less than 60 days. These pesticides may have low potential to leach through soil but are mobile in runoff sediment. Leaching studies, which are not adequate by Agency standards, indicate that chlordimeform and chlordimeform HCl are relatively immobile in muck, silt loam, silty clay, sandy loam, silty clay loam and clay soils. The available data are insufficient to fully characterize the leaching potential and other environmental fate characteristics although, the potential for contamination of ground water is thought to be low.

Ecological Effects

Chlordimeform is moderately toxic to both coldwater and warmwater fish species, whereas available data on the formulated EP products suggest that they are highly toxic to coldwater fish and moderately toxic to warmwater fish. Chlordimeform is moderately toxic to shrimp and oysters. There are insufficient toxicity data on freshwater aquatic invertebrates and marine/estua[illegible] fish.

Emulsifiable concentrate end-use formulations of chlordimeform are slightly to moderately toxic to birds. Other pertinent avian toxicity data are unavailable.

E. Regulatory Position and Rationale

Based on the review and evaluation of available data and other relevant information on chlordimeform and chlordimeform HCl, the Agency has made the following determinations:

Position 1

All products containing either chlordimeform or chlordimeform HCl as sole active ingredients may continue to be registered for sale, distribution, reformulation and use only on cotton and subject to the terms and conditions specified in this Guidance Document. Registrants must agree to develop and provide additional data as specified in tables A and B in order to maintain existing registrations or to obtain new registrations. Additionally, the Agency is planning to proceed with a Special Review of chlordimeform and chlordimeform HCl because of the carcinogenic potential indicated above.

Rationale:

As discussed above in the Current Science Assessment section, four mouse studies demonstrated a dose response for the formation of hemangioendothelioma, hemangiosarcomas or hemangiomas from lifetime feeding of chlordimeform HCl or one of two known animal metabolites. The weight of the evidence from these

four studies fully support the conclusion of carcinogenicity. Further, mutagenicity studies with positive responses support this carcinogenic response. Worker exposure studies have shown the presence of one of these oncogenic metabolites in urine following exposure to either chlordimeform or chlordimeform HCl. From these findings, the Agency has classified these pesticides as B2 -- a probable human carcinogen. Applicator carcinogenic risk ranges from about 10^{-3} to 10^{-6}, when application is made under the required stringent worker protection measures. The preliminary dietary risk from the cotton use ranges from about 10^{-4} to 10^{-7}, depending upon assumptions used in the risk calculations. Therefore, as a result of these findings and conclusions, the Agency is initiating its Special Review of risks and benefits for these two pesticides.

Position 2

The Agency is requiring the submission of additional data in order for the Agency to complete its scientific and regulatory assessment of chlordimeform and chlordimeform HCl. The required additional data are to be from studies on analytical chemistry, plant and animal metabolism, animal reproduction, worker exposure, environmental fate and avian, freshwater invertebrate and fish toxicity.

Rationale

The current data base is inadequate to enable the Agency to assess fully the potential effects of chlordimeform and chlordimeform HCl on man and the environment. Therefore, additional data are required in order that this assessment can be made.

The available chemistry data indicate that many of the plant and animal metabolites may become conjugated with tissues. Animal metabolism data suggest that up to 95% of all parent and metabolite compounds are excreted within three days. Nevertheless, the remaining metabolites have not been adequately identified or quantified. Thus, the Agency is unable to determine whether or not they may be of toxicological concern. New studies and improved detection methods are required so that the Agency can better assess the metabolism of chlordimeform and chlordimeform HCl in plants and animals and in so doing can refine its assessment of exposure and the adequacy of established tolerances.

The reproduction data requirement has not been satisfied because necessary detail and raw data were omitted from the submission. These deficiencies impede the Agency's effort to make a complete assessment of the adequacy of the study and chlordimeform's and chlordimeform HCl's potential effects on animal reproduction. However, the available data do not suggest any adverse reproduction effects. If these deficiencies cannot be corrected, a new reproduction study will be required. Except for this data gap and the animal metabolism deficiency discussed above, all other toxicology requirements are satisfied.

Additional information is being required on dermal exposure to workers involved in chlordimeform and chlordimeform HCl applications to cotton. These data are needed in order for the Agency to refine exposure and risk estimates. Extensive data have been submitted to

the Agency; however, these data are difficult to interpret into total body exposure. The majority of these data are of metabolite residue values from workers' urine samples. There are also some data on dermal exposure. However, there are serious flaws with all of the studies and the manner in which the data were reported. Therefore, the Agency is requiring that these studies be upgraded by Ciba-Geigy and Nor-Am, if possible. Otherwise, additional studies will be required.

The Agency is requiring additional environmental fate data because the available data, as summarized in the Current Science Assessment above, are not sufficient to fully assess the environmental fate of these pesticides, including a complete characterization of their leaching and ground water contamination potential.

The current ecological effects data base on chlordimeform and chlordimeform HCl is insufficient to adequately characterize the potential toxicity to birds, freshwater invertebrates and estuarine/ marine fish. Acute oral and dietary toxicity studies on birds are required so that the Agency can assess the hazard potential to avian species from consuming food items contaminated with chlordimeform and chlordimeform HCl associated with cotton field applications. An avian reproduction study is required because of the potential exposure from multiple applications to cotton fields prior to and during the breeding season of several upland game species which inhabit cotton fields. Data on the toxicity to freshwater invertebrates and marine/estuarine fish are required because of the pesticides'

potential to runoff into and be used near aquatic systems. Depending upon the Agency's conclusions from its assessment of these required data, additional studies, including field testing for birds and aquatic organisms, may be required. Also, these conclusions may lead to the requirement for an endangered species label warning.

Position 3

The Agency is imposing current and new label requirements that will, in effect, help to reduce and minimize worker exposure and therefore, decrease the carcinogenic risk and other hazards to workers. All end-use chlordimeform or chlordimeform HCl products will continue to be classified as Restricted-Use and the restricted-use label statement will include a carcinogenicity statement as the reason for the classification. A cancer warning statement will also be retained for the manufacturing-use product labels.

All end-use products will continue to be labeled for the cotton use only and with the use restrictions of: 1) closed systems for mixing and loading, 2) protective clothing, 3) 0.25 lb ai/A application rate, 4) training and monitoring programs for workers and 5) Restricted Use classification.

The Agency is changing the field reentry interval when protective clothing is not required to be worn from 1 day to 5 days.

Rationale

For the reintroduction of chlordimeform and chlordimeform HCl in 1978, the Agency required that all products be labeled with the restricted use statement. In 1982, Ciba-Geigy proposed to add a cancer warning statement to its end-use product labels. In response to this proposal the Agency imposed a cancer warning statement for labels of all registered end-use and manufacturing-use products. Since the Agency has determined that these active ingredients are carcinogens, continuation of the restricted use requirement and a cancer statement are warranted. The Agency also believes that combining these two label statements on the EP label will be more informative by providing the reason that the products are classified for restrictive use.

The Agency believes that the use of closed systems, protective clothing, a maximum application rate of 0.25 lb ai/A, and worker training and monitoring programs, as well as the restricted use classification and the cancer statement discussed above, will result in reduced exposure to chlordimeform and chlordimeform HCl. These use restrictions provide the maximum protection from exposure tha' 'an reasonably be obtained at this time.

The Agency is increasing the reentry interval because the data base for dislodgeable residues of chlordimeform on cotton leaves indicates that by five days the remaining dislodgeable residues have dissipated to an acceptable exposure level.

After one day, the remaining dislodgeable residues are 0.17 ug/cm^2, or about 8-fold greater than the calculated allowable exposure level. Whereas, after five days the residues are 0.02 ug/cm^2, which are low enough to give a field worker an exposure that is equal to or less than the calculated allowable exposure level for these pesticides. Therefore, the Agency believes it is prudent to lengthen the reentry period without the use of protective clothing to minimize exposure to these chemicals.

The specific label statements that are imposed under these regulatory positions are presented in section F below.

Position 4

Other use/label restrictions are imposed. All EP labels must have use restrictions requiring a 21-day preharvest interval, prohibiting the feeding of treated foliage or gin trash to livestock, and prohibiting the grazing of livestock in treated areas. Also, all EP labels must have a statement in the environmental hazards section that warns of these pesticides' toxicity to fish.

Rationale

The residue chemistry data base supports the established tolerances associated with the use on cotton (refer section G, Tolerance Reassessment Summary, below) provided that the above restrictions are followed. The specific restrictions are presented in section F below. The livestock feeding restriction does not include the feeding of cottonseed hulls and oil to livestock. Both cottonseed

hulls and oil have established tolerances which are supported by adequate residue data. Also, the tolerances for meat, milk, poultry and eggs are supported by data which demonstrate that the cottonseed hulls and oil with residues at their tolerance levels can be fed to livestock. Similar data do not exist for foliage or gin trash, hence the restriction.

A fish toxicity label statement is required because the acute toxicity data on an EP product formulation demonstrated high acute toxicity to a representative coldwater fish species (rainbow trout) and moderate toxicity to a warmwater species (bluegill sunfish). Also, environmental fate data suggest that these pesticides are mobile in runoff sediment which may contaminate aquatic habitats. Therefore, a fish toxicity statement is required to inform users of this potential hazard. The specific label requirement is presented in Section F below.

Position 5

Registrants of end-use products must submit revised labeling which incorporates the label changes specified in Section F below.

Rationale

The Agency believes that the label requirements prescribed in this Guidance Document should promote reduced exposure and hazards to workers and to the environment. As discussed above, the extensive use restrictions, including the use of protective clothing, closed systems and use by or under supervision of

certified applicators, should reduce dermal exposure to workers and, the environmental precautions should aid in reducing hazards to fish and wildlife.

Position 6

The Agency will propose the revocation of established tolerances of chlordimeform and chlordimeform HCl associated with those uses which were voluntarily withdrawn and removed from labels in 1978. The associated crops are listed above in Section B.

Rationale

The subject crop uses have been withdrawn since 1978; therefore, it is not necessary to maintain tolerances for these uses. It is reasonable to assume that all existing stocks of products which were labeled for these uses have been used or recalled by the registrants and therefore, it is unlikely these crops would have residues in the future. Also, tolerance revocation would provide a means of restricting the importation of commodities with residues.

D. Criteria for Registration Under This Standard

To be covered under this Guidance Document, products must contain chlordimeform or chlordimeform HCl 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 application for registration or reregistration of manufacturing-use products subject to this Guidance Document must comply with all terms and conditions described herein, 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).

E. Acceptable Ranges and Limits

Product Composition Standard

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

Acute Toxicity Limits

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

Use Patterns

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

F. Required Labeling

All manufacturing-use and end-use chlordimeform and chlordimeform HCl products must bear appropriate labeling as specified in 40 CFR 162.10. The Guidance Document for this Standard contains information on label requirements.

Ingredient Statement

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

Chlordimeform: N'-(4-Chloro-o-tolyl)-N,N-dimethyl formamidine..... __%

Chlordimeform hydrochloride: N'-(4-chloro-o-tolyl)-N,N-dimethyl formamidine hydrochloride..... __%

Statements For End-Use Products

1. All end-use products must bear the restricted-use statement with the second paragraph in caps as it appears below:

RESTRICTED USE PESTICIDE

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

BECAUSE CHLORDIMEFORM HAS BEEN SHOWN TO CAUSE CANCER IN LABORATORY MICE, THIS PRODUCT MAY BE APPLIED ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION. USE OF PROTECTIVE CLOTHING AND EQUIPMENT AND FOLLOWING THE USE PRECAUTIONS BELOW CAN REDUCE RISK.

2. The reentry statement below must appear in the use directions of labels of all products with directions for use on cotton:

Do not reenter treated areas for 5 days without wearing protective clothing.

3. The preharvest interval, feeding and grazing restrictions below must appear in the use directions of labels of all products with directions for use on cotton:

To avoid illegal residues, 1) do not apply within 21 days of picking, including when mixed with other pesticides 2) do not feed foliage from treated cotton plants or crop residues, such as gin trash to livestock and 3) do not allow livestock to graze treated areas.

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

During mixing/loading or application wear a protective suit which has long sleeves and long pants. Wear chemical resistant gloves, a hat, boots and goggles or a face shield. A helmet

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

5. The following environmental hazards statement must appear on each end-use product label in the Environmental Hazards section:

> This product is toxic to fish. Do not apply directly to water or wetlands. Drift or runoff from the treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Statements For Technical and Manufacturing-Use Products

1. The following environmental hazards statement must appear on each technical and manufacturing-use product label in the Environmental Hazards section:

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

2. The following cancer warning must appear in caps on labels of technical and manufacturing-use products:

> THIS PRODUCT HAS BEEN SHOWN TO CAUSE CANCER IN LABORATORY ANIMALS. THE USER MUST READ AND FOLLOW ALL PRECAUTIONARY STATEMENTS AND INSTRUCTIONS.

G. Tolerance Reassessment Summary

40 CFR section 180.285 and 21 CFR sections 193.60 and 561.80 list the various established tolerances for chlordimeform and chlordimeform HCl and their metabolites that contain the 4-chloro-o-toluidine moiety. These are as follows:

Crop	Tolerances(ppm)
Pears	12.
*Cottonseed oil	5.
*Cottonseed hulls	10.
Cherries	5.
Nectarines	5.
Peaches	5.
Plums, incl. fresh prunes	4.
Prunes, dried	15.
Apples	3.
Apple pomace	25.
Broccoli	2.
Brussel sprouts	2.
Cabbage, sauerkraut	2.
Cauliflower	2.
Tomatoes	1.
*Cattle	0.25
*Goats	0.25
*Hogs	0.25
*Poultry	0.25
*Sheep	0.25
*Horses	0.25
*Eggs	0.05
*Milk & Dairy Products	0.05
Walnuts	0.10

*Tolerances which are associated with the application to cotton.

The above tolerances were established between 1968 and 1976 and were based on a chronic toxicity data base that included subchronic

feeding, teratology, reproduction and chronic feeding studies. A dog chronic feeding study was used to establish a no-observable-effect level (NOEL) for both active ingredients. This NOEL was 6.25 mg/kg/day, which factored into an Acceptable Daily Intake (ADI) of 0.062 mg/kg/day.

A rereview of the chronic toxicology data base discloses a lower NOEL (0.1 mg/kg/day) based on a more recent rat chronic feeding study and upon the formation of methemoglobin.

The new ADI is calculated to be 0.001 mg/kg/day. The percent of the new utilized ADI based upon all previously issued tolerances is 671 percent for the general population. However, since the current label carries use directions for cotton only, the percent of the utilized ADI, based upon the application to cotton and the associated animal product tolerances, is 134 percent for the general population. This latter calculation is based on the Agency's new Tolerance Assessment System (TAS). However, from the TAS analysis it suggests that children, of the 1 through 6 years age group, have a dietary intake that exceeds the current ADI by 307 percent. The Agency believes that this intake value is artificially high because it is derived from the assumption that all dietary items will be at tolerance residue levels. This unrealistic intake, which was explained in the Dietary Exposure section of the Current Science Assessment, below, suggests that the realistic dietary intake is less than the ADI.

The metabolism of chlordimeform has not been adequately described. Should the required metabolism data indicate the presence of additional metabolites of concern, the tolerance definition will be revised accordingly. Also, the Agency will propose the revocation of those tolerances for which there are no associated registered uses.

Codex has established Maximum Residue Limits which are temporary because Codex considered the ADI to be temporary. Codex is not permitting residues above the level of detection (0.05 ppm) on or in cotton seed and cotton seed oil, meat from cattle, pigs and sheep, poultry, milk and milk products. Therefore, no harmonization with U.S. tolerances is possible except for milk and milk products.

There are no Canadian or Mexican tolerances for chlordimeform.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required ? Yes	Are Data Required ? No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below [2]
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	R	[x]	[ ]	3	6 Months
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]	[ ]	5	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	[x]	[ ]	6	12 Months
62-2 - Certification of Limits	TGAI	R	[x]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limit	TGAI	R	[x]	[ ]		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

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required ? Yes	Are Data Required ? No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below [2]
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-5 - Melting Point	TGAI	R	[x]	[ ]		6 Months
63-6 - Boiling Point	TGAI	R	[x]	[ ]		6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[x]	[ ]		6 Months
63-8 - Solubility	TGAI or PAI	R	[x]	[ ]	7	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]	[ ]		6 Months
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	Reserved [8]			6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required ? Yes	Are Data Required ? No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below [2]
§158.120 Product Chemistry (Continued)						

1 Test substances are for both chlordimeform and chlordimeform hydrochloride. TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required.
2 Data must be submitted within the indicated timeframes which begin on the date of this Guidance Document.
3 Current data on the manufacturing of technical chlordimeform lacks essential detail and is considered out-of-date.
4 All manufacturing procedures now in actual use must be submitted for each registered technical product.
5 The Agency has no data on the formation of unintentional ingredients. Data are required on each impurity believed to be present at $\geq$ 0.1%, based on the knowledge of starting materials, all possible chemical reactions and any contamination. Also, the possibility of the presence or absence of nitrosamines must be addressed.
6 Current data are obsolete, therefore up-to-date data must be submitted on the identity of every ingredient present or intentially added, if $\geq$ 0.1% by weight. Five or more representative samples must be analyzed by appropriate method(s) and described in detail with a statement of the precision and accuracy, including methods for nitrosamines if present. Certification of limits of all ingredients, including impurities, and the analytical method(s) and data are required.
7 Quantitative data are required.
8 Reserved pending Agency decision as to whether the samples are required.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission [2]
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	Yes	00098977, 00100811 00099014, 00073479	No
171-3 - Directions for Use	--		00104272, 00103369	No
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00098991, 00087052 00087053, 00087056	Yes[3] 18 Months
- Livestock	PAIRA and Plant Metabolites	Partial	00087050, 00087051 00087054, 00087055	Yes[3,4] 18 Months
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	No		Yes[5] 15 Months
- Animal residues	TGAI and Metabolites	No		Yes[5] 15 Months
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Cotton				
-- Crop field trials	TEP	Yes	00097467, 00086695 00036949, 00080099 00069682, 00099031 00102410, 00099011 00098957, 00087046	Reserved

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission [2]
§158.125 Residue Chemistry - Continued				
-- Processed Food/Feed	EP	Yes	00098959	No[6]
-- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Yes	00087045, 00087049 00087059, 00098959	No[6]
Other crops[7]				

[1] Composition is for both chlordimeform and chlordimeform hydrochloride. TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

[2] Data must be submitted within the indicated timeframe which begins on the date of the Guidance Document.

[3] Existing data indicate that many of the plant and animal metabolites are conjugated with tissues. These conjugated metabolites remain unidentified and may be of toxicological concern. These metabolites must be identified and quantified.

[4] Data must be submitted on poultry metabolism. The requirement on swine metabolism is reserved until the review of poultry data.

[5] Analytical methods for plant and animal metabolites must be improved to identify conjugated metabolites that may be of toxicological concern.

[6] Additional data may be required in the future if the required plant and animal metabolism studies show new metabolites of toxicological concern.

[7] Tolerances exist for the additional following crops: apples, broccoli, brussels sprouts, cabbage, cauliflower, cherries, nectarines, peaches, pears, plums or fresh prunes, tomatoes and walnuts. However, the adequacy of the supporting data for these tolerances is not presented here because there are no longer registered uses for these crops and because the Agency intends to revoke these tolerances.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA base	A	Partial	00098998	Yes[4]	9 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA base	A	No		Yes[5]	9 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	9 Months
161-3 - On soil	TGAI or PAIRA base	A	No		Yes[5]	9 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA base	A	No		Yes[5]	27 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA base	A	No		Yes[5]	27 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA base	A	Partial	00044017	Yes[5]	12 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission[3]
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP base	A	No		Yes[5]	27 Months
	TEP HCl	A	No		Yes[5]	27 Months
164-5 - Soil, Long-term	TEP base	A	No		Yes[5]	50 Months
	TEP HCl	A	No		Yes[5]	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA base	A	No		Yes[5]	39 Months
	PAIRA HCl	A	No		Yes[5]	39 Months
165-2 - Rotational Crops (Field)	TEP base	A	No		Yes[5]	50 Months
	TEP HCl	A	No		Yes[5]	50 Months
165-4 - In Fish	TGAI or PAIRA base	A	No		Yes[5]	12 Months
	TGAI or PAIRA HCl	A	No		Yes[5]	12 Months

[1] Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
[2] The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
[3] Data must be submitted within the indicated time frames which begin on the date of the Guidance Document.
[4] Data are required for chlordimeform HCl.
[5] Studies may be conducted with either chlordimeform or chlordimeform HCl to satisfy the data requirement.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50}	TGAI base	A	Yes	00066882,00082200,0098918, 00066883	No
	TGAI HCl	A	Yes	00066886,00082202,0082203	No
81-2 - Dermal LD_{50}	TGAI base	A	No[4]		No
	TGAI HCl	A	Yes	00078159	No
81-3 - Inhalation LC_{50}	TGAI base	A	No[4]	00066822	No
	TGAI HCl	A	Yes	00066872	No
81-4 - Primary Eye Irritation	TGAI base	A	Yes	00066884	No
	TGAI HCl	A	No[4]		No
81-5 - Primary Dermal Irritation	TGAI base	A	Yes	00098901	No
	TGAI HCl	A	Yes	00098919	No
81-6 - Dermal Sensitization	TGAI base	A	Yes	00098919,00098901	No
	TGAI HCl	A	Yes	00066872	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent and Non-Rodent	TGAI base	A	Yes	00098914,00098913	No
	TGAI HCl	A	No[4]		No
82-2 - 21-Day Dermal	TGAI base	A	Yes	00066872	No
	TGAI HCl	A	Yes	00098920	No

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species:					
- Rodent	TGAI base	A	Yes	00067569	No
	TGAI HCl	A	Yes	00072168	No
- Non-rodent (Dog)	TGAI base	A	Yes	00066887	No
	TGAI HCl	A	No[4]		No
83-2 - Oncogenicity - 2 species:					
- Rat	TGAI base	A	Yes	00067569,00072168,00097888	No
	TGAI HCl	A		00079920,00070981,00070982 00070983	No
- Mouse	TGAI base	A	Yes	00081013,00081041,00070979	No
	TGAI HCl	A		00070980,00070983	No
83-3 - Teratogenicity - 2 species:					
- Rat	TGAI base	A	Yes	00079934	No
	TGAI HCl	A	No[4]		No
- Rabbit	TGAI base	A	Yes	00082198	No
	TGAI HCl	A	No[4]		No
83-4 - Reproduction - Rat 2-generation	TGAI base	A	Partial	00066881,00082199,00099009	Yes[5] 6 Months
	TGAI HCl	A	No[4]		Yes[5] 6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission [3]
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI base	A	Yes	00079923, 00079927,00087382 00079932,00079928 00042258,00079931,	No	
	TGAI HCl	A	Yes	00079924	No	
SPECIAL TESTING						
85-1 - Animal Metabolism	TGAI	A	Partial	00087050,00087051 00087054,00087055	Yes[6]	18 Months

[1] Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
[2] The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
[3] Data must be submitted within the indicated time frames which begin on the the date of the Guidance Document.
[4] Toxicology data on the technical base will support the technical HCl and vice versa.
[5] The reproduction study did not contain enough data to make an adequate evaluation. The registrant is required to submit the raw data and additional detail within 6 months. If these data are not available or if they do not fulfill the requirements, a new reproduction study will be required.
[6] Refer to GENERIC DATA REQUIREMENTS for residue chemistry, requirement 171-4, above, for an explanation of this entry.
[7] Data applies to both the CDM base and salt form.
[8] Presently not a requirement. May have to be addressed depending upon the results of the environmental fate analysis.
[9] This analysis was performed on CDM base, salt and metabolite data.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission[3]
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	Yes	00099029	No	
132-1 - Soil Dissipation	TEP	A	No		No	
133-3 - Dermal Exposure	TEP	A	Partially	00085918 00099027	Yes[4]	15 Months
133-4 - Inhalation Exposure	TEP	A	No		No	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No		No	
201-1 - Drift Field Evaluation	TEP	A	No		No	

[1] Composition: TEP = Typical end-use product of either chlordimeform or chlordimeform HCl.
[2] The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
[3] Data must be submitted within the indicated time frames which begin on the date of the Guidance Document.
[4] Data on file with the Agency lacks sufficient detail and samples or it is inappropriate in which to determine total body exposure. A new dermal exposure study is required. A protocol must be submitted and accepted by the Agency.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI base	A	No		Yes 9 Months
	TGAI HCl	A	No		Yes[4] 9 Months
71-2 - Avian Dietary LC_{50}					
a. Waterfowl	TGAI base	A	Yes	00022923	No
	TGAI HCl	A	No		Reserved[5] 9 Months
b. Upland Game	TGAI base	A	Yes	00022923	No
	TGAI HCl	A	No		Yes[5] 9 Months
71-4 - Avian Reporduction					
a. Waterfowl	TGAI base	A	No		Yes[6] 24 Months
	TGAI HCl	A	No		Yes[6] 24 Months
b. Upland Game	TGAI base	A	No		Yes[6] 24 Months
	TGAI HCl	A	No		Yes[6] 24 Months
71-5 - Simulated and Actual Field Testing for Mammals and Birds	TEP	A	No		Reserved[7]

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]	
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
72-1 - Freshwater Fish LC_{50}						
a. Warmwater	TGAI base	A	Yes	GS-0144-012	No	
	TGAI HCl	A	Partial	00085345	No[8]	
b. Coldwater	TGAI base	A	Yes	GS-0144-012	No	
	TGAI HCl	A	Partial	00102214	No	
72-2 - Acute LC_{50} to Freshwater Invertebrates	TGAI base	A	No		Yes	9 Months
	TGAI HCl	A	No		Yes	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
a. Fish	TGAI base	A	No		Yes[9]	12 Months
	TGAI HCl	A	No		No[8]	
b. Shrimp	TGAI base	A	Yes	00078138	No	
	TGAI HCl	A	No		No[8]	
c. Oyster	TGAI base	A	Yes	00078138	No	
	TGAI HCl	A	No		No[8]	

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms - Continued					
AQUATIC ORGANISMS TESTING					
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-cycle	TGAI base	A	No		Reserved[7]
	TGAI HCl	A	No		Reserved[7]
72-5 - Fish - Life-Cycle	TGAI base	A	No		Reserved[7]
	TGAI HCl	A	No		Reserved[7]
72-6 - Aquatic Organism Accumulation	TGAI (base and HCl), PAI or degradation product	A	No		Reserved[7]
72-7 - Simulated or Actual Field Testing					
a. Aquatic Organisms	TEP	A	No		Reserved[7]

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms - 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, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3 Data must be submitted within the indicated time frames which begin on the date of the Guidance Document.

4 Studies on the TGAI base can be used to support data requirements for chlordimeform TGAI HCl.

5 Most existing data suggest that the HCl form is not more toxic to birds than the base. However, an avian dietary LC_{50} study on an upland game bird species is required to confirm this. Depending on the results, further testing of the HCl form may be required.

6 Data are required because multiple applications are authorized in fields immediately preceeding, and during, breeding season for several upland game species utilizing cotton fields for feeding/nesting. Data requirements for chlordimeform HCl can be satisfied by the use of chlordimeform base data.

7 Requirement is reserved pending outcome of lower tier testing requirements for fish and aquatic invertebrates, or in the case of avian studies, reproduction testing on birds.

8 Available data on fish toxicity of chlordimeform HCl, although no adequate by current test standards, is sufficient to indicate that chlordimeform HCL is less toxic to fish than chlordimeform base. Therefore, additional data on chlordimeform HCl is not required.

9 Data are required because use pattern encompasses greater than 300,000 acres in coastal counties of the U.S., therefore creating a potential to impact marine/estuarine organisms.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP base		No		No[4]
	EP HCl		No		No[4]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI base		No		No[4]
	TGAI HCl		No		No[4]
122-1 - Vegetative Vigor	TGAI base		No		No[4]
	TGAI HCl		No		
122-2 - Aquatic Plant Growth	TGAI base		No		No[4]
	TGAI HCl		No		No[4]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI base		No		No[4]
	TGAI HCl		No		No[4]
123-1 - Vegetative Vigor	TGAI base		No		No[4]
	TGAI HCl		No		No[4]
123-2 - Aquatic Plant Growth	TGAI base		No		No[4]
	TGAI HCl		No		No[4]

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.150 Plant Protection (continued)					
TIER III					
124-1 - Terrestrial Field	TEP base		No		No[4]
	TEP HCl		No		No[4]
124-2 - Aquatic Field	TEP base		No		No[4]
	TEP HCl		No		No[4]

1 Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2 The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3 Data must be submitted within the indicated time frame which begins on the date of the Guidance Document.
4 These requirements are generally waived unless it is believed there is a phototoxicity problem.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.155 Nontarget Insects					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI base	A	Yes	00028772	No
	TGAI HCl	A	No		No[4]
141-2 - Honey bee - toxicity of residues on foliage	TEP base	A	Yes	00077760	No
	TEP HCl	A	No		No[4]
141-4 - Honey bee subacute feeding study	(Reserved)[5]				
141-5 - Field testing for pollinators	TEP base	A	No		No[6]
	TEP HCl	A	No		No[6]
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)[7]				
142-1 - Aquatic insect life-cycle study	(Reserved)[7]				

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

§ 158.155 - Non-target Insects - Continued		
142-3	Simulated or actual field testing for aquatic insects	(Reserved)[7]
143-1 thru 143-3	NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[7]

1 Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2 The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3 Data must be submitted within the indicated time frame which begins on the date of the Guidance Document.
4 It is assumed that toxicity of chlordimeorm HCl will be similar to the base form, therefore no additional data on chlordimeform HCl is required.
5 Requirement is reserved pending deveolopment of test methodology.
6 As lower tier tests indicate low toxicity to bees, no further testing is required.
7 Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE

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

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE

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

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

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE

Data Requirement	Composition[1]		Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [2]
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity	MP base	A	Yes	00066882,00082200 00066883,00098918	No
	MP HCl	A	Yes	00066886	No
81-2 - Acute Dermal Toxicity	MP base	A	No		No[3]
	MP HCl	A	Yes	00078159	No
81-3 - Acute Inhalation Toxicity	MP base	A	No	00066872	No[3]
	MP HCl	A	Yes	00066872	No
81-4 - Primary Eye Irritation	MP base	A	Yes	00066884	No
	MP HCl	A	No		No[3]
81-5 - Primary Dermal Irritation	MP base	A	Yes	00098901	No
	MP HCl	A	Yes	00098919	No
81-6 - Dermal Sensitization	MP base	A	Yes	00098919,00098901	No
	MP HCl	A	Yes	00066872	No

[1] Composition: MP = Manufacturing-use product.
[2] Data must be submitted within the indicated time frames which begin on the date of the Guidance Document.
[3] Acute toxicology data on the technical base will support the technical HCl and vice versa.

c059701

CHLORDIMEFORM*

TYPE PESTICIDE: Insecticide, Plant Regulator

FORMULATIONS:
Tech (90%, 95%, 97%)
EC (4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not mix or use with alkaline materials. Do not reenter treated areas for 5 days without protective clothing. During mixing/loading or application wear a protective suit which has long sleeves and long pants. Wear chemical resistant gloves; a hat, boots and goggles or face shield. A helmet with visor may be substituted for the hat and goggles during aerial application. Mixer/loaders must also wear a chemical resistant apron when handling the concentrated product. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab or cockpit with properly filtered air supply.
Chlordimeform is toxic to fish. Do not apply directly to water or wetlands. Drift or runoff from the treated areas may be hazardous to aquatic organisms in neighboring areas.
Chlordimeform must be transferred and mixed using closed system equipment. A closed system is defined as appropriate connections, meters, pumps, and plumbing designed to eliminate human contact. Do not use open mixing vats or open pouring.

Agricultural Crop Tolerances (other than those listed in the text):

Apple	3 ppm
Apple (dried apple pomace)	25 ppm
Broccoli	2 ppm
Brussels Sprouts	2 ppm
Cabbage	2 ppm
Cauliflower	2 ppm
Cherries	5 ppm
Nectarine	5 ppm
Peach	5 ppm
Pear	12 ppm
Plums (fresh prunes)	4 ppm
Tomatoes	1 ppm
Walnut	0.1 ppm

Livestock and Poultry Tolerances:

Cattle (fat, meat, meat byproducts)	0.25 ppm
Eggs	0.05 ppm
Goats (fat, meat, meat byproducts)	0.25 ppm
Hogs (fat, meat, meat byproducts)	0.25 ppm
Horses (fat, meat, meat byproducts)	0.25 ppm
Milk	0.05 ppm
Poultry (fat, meat, meat byproducts)	0.25 ppm
Sheep (fat, meat, meat byproducts)	0.25 ppm

*Fundal EC
Galecron EC
N'-(4-chloro-o-tolyl)-N,N-dimethylformamidine

Issued: 8-19-82 III-059701-1
Provisional Update: 9-17-84

CHLORDIMEFORM

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/28007AA	Cotton		5 ppm (cottonseed) 10 ppm (cottonseed hulls) 21 day preharvest interval through 0.25 pound per acre for foliar application. 24 hour reentry period. Do not feed treated foliage or gin trash to livestock. Do not allow livestock to graze in treated areas. Unless otherwise specified, apply in a minimum of 1 gallon of water per acre by aircraft or ground equipment using low drift nozzles.
ITBCBOA	Bollworm (including eggs)	0.125-0.25 lb/A (4 lb/gal EC)	Use limited to cotton growing states other than AZ and CA. Foliar application. Repeat at 3 to 5 day intervals when moth flights begin and/or when eggs appear. Continue as long as eggs are present. Apply the low rate when pest populations are low or egg deposition is just starting.
ITBCBNA	Tobacco budworm (including eggs)	0.25 lb/A (4 lb/gal EC)	
ITBCBOA	Bollworm (including eggs)	0.125-0.25 lb/A (4 lb/gal EC)	Use of the dosage range is limited to cotton growing states other than AZ and CA. Use of the high rate is limited to AZ and CA. Foliar application. Apply as a tank mix with other insecticides when egg hatch occurs because of delayed application or other causes, or when it is necessary to begin application in a field where the target or other pests have reached economic levels. Tank mix with Bacillus thuringiensis, dimethoate, dicrotophos, methyl parathion, azinphosmethyl, monocrotophos, chlorpyrifos, phosmet, methomyl, methidathion, acephate, polyhedral inclusion bodies of Heliothis nuclear polyhedrosis virus, diflubenzuron, fenvalerate, permethrin, profenofos, sulprofos, methyl parathion plus EPN, and methyl parathion plus toxaphene.
ITBCBNA	Tobacco budworm (including eggs)		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
PZZZZZA	Increase yield	0.125-0.25 lb/A (4 lb/gal EC)	Increase yield. Foliar application. Apply as a broadcast spray. Apply 4 to 6 times at 5-7 day intervals beginning at first pinhead square formation (5 to 7 true leaf stage). Yield increase however, may not occur if plants are under stress during treatment.
	AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS		
9001500 AAAAAAA	Aerial Application		
	--		Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton
9900300 AAAAAAA	Tank Mix		
	--		Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton

CHLORDIMEFORM

Listing of Registered Pesticide Products by Formulation

&095.0001 95% technical chemical
chlordimeform (059701)
000100-00560

&097.0001 97% technical chemical
chlordimeform (059701)
002139-00105

&090.0001 90% formulation intermediate
chlordimeform (059701)
002139-00106

&104.0012 4 lb/gal emulsifiable concentrate
chlordimeform (059701) plus aromatic petroleum distillate (006601)
000279-02852

chlordimeform (059701) plus xylene range aromatic solvent (086803)
000100-00551

9999999 State Label Registrations

AZ Reg. No.
002139-04356

CA Reg. No.

000100-04301	000279-09169	000279-09170	002139-04333
002139-04337	002139-04344		

FL Reg. No.
004841-06125

HI Reg. No.
007843-08573

ID Reg. No.
002139-04343

LA Reg. No.

004841-06123	004841-06124	004841-06126	004841-06128
004841-06129	004841-06131	004841-06134	004841-06136
004841-06137	004841-06139	004841-06167	004841-06168

NV Reg. No.
002139-04341

OR Reg. No.

002139-04328	002139-04331	002139-04345	002139-04355

Issued: 8-19-82 III-059701-4

Listing of Registered Pesticide Products by Formulation (continued)

VT Reg. No.
002139-04340 002139-04346

WA Reg. No.
002139-04329 002139-04330 002139-04342 002139-04352

Appendix A

Listing of Common Chemical Names Used on the Entry

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
035201	dicrotophos (ISO)	dimethyl phosphate ester with 3-hydroxy-N,N-dimethyl-cis-crotonamide
041801	EPN	O-ethyl O-(p-nitrophenyl)phenyl-phosphonothioate
053501	methyl parathion	O,O-dimethyl O-p-nitrophenyl phosphorothioate
058001	azinphosmethyl (ISO)	O,O-dimethyl S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl] phosphoro- dithioate
058901	monocrotophos (ISO)	dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide
059201	phosmet (BSI)	N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate
109301	fenvalerate (ISO)	cyano(3-phenoxyphenyl)methyl 4-chloro-alpha-(1-methylethyl)benzeneacetate
111501	sulprofos	O-ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number

TERRESTRIAL FOOD CROP

(Agricultural Crops)

/28007AA Cotton
ITBCBOA Bollworm (including eggs)
PZZZZZA Increase yield
ITBCBNA Tobacco budworm (including eggs)
(4 lb/gal EC)
000100-00551

c059702

CHLORDIMEFORM HYDROCHLORIDE*

TYPE PESTICIDE: Insecticide, Plant Regulator

FORMULATIONS:
Tech (95%, 97%)
SC/S (95%, 97%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not mix or use with alkaline materials. Do not reenter treated area for 5 days without protective clothing. During mixing/loading or application wear a protective suit which has long sleeves and long pants. Wear chemical resistant gloves; a hat, boots and goggles or face shield. A helmet with visor may be substituted for the hat and goggles during aerial application. Mixer/loaders must also wear a chemical resistant apron when handling the concentrated product. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab or cockpit with properly filtered air supply.
Chlordimeform is toxic to fish. Do not apply directly to water or wetlands. Drift or runoff from the treated areas may be hazardous to aquatic organisms in neighboring areas.
Chlordimeform must be transferred and mixed using closed system equipment. A closed system is defined as appropriate connections, meters, pumps, and plumbing designed to eliminate human contact. Do not use open mixing vats or open pouring.

Agricultural Crop Tolerances (other than those listed in the text):

Apple	3 ppm
Apple (dried apple pomace)	25 ppm
Broccoli	2 ppm
Brussels Sprouts	2 ppm
Cabbage	2 ppm
Cauliflower	2 ppm
Cherries	5 ppm
Nectarine	5 ppm
Peach	5 ppm
Pear	12 ppm
Plums (fresh prunes)	4 ppm
Tomatoes	1 ppm
Walnut	0.1 ppm

Livestock and Poultry Tolerances:

Cattle (fat, meat, meat byproducts)	0.25 ppm
Eggs	0.05 ppm
Goats (fat, meat, meat byproducts)	0.25 ppm
Hogs (fat, meat, meat byproducts)	0.25 ppm
Horses (fat, meat, meat byproducts)	0.25 ppm
Milk	0.05 ppm
Poultry (fat, meat, meat byproducts)	0.25 ppm

*Fundal SP
Galecron SP
N'-(4-chloro-o-tolyl)-N,N-dimethylformamidine hydrochloride

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Provisional Update: 9-11-85

CHLORDIMEFORM HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
007AA	Cotton		5 ppm (cottonseed) 10 ppm (cottonseed hulls) 21 day preharvest interval through 0.24 pound per acre for foliar application. 24 hour reentry period. Do not feed treated foliage or gin trash to livestock. Do not allow livestock to graze in treated areas. Unless otherwise specified, apply in a minimum of 1 gallon of water per acre by aircraft or in a minimum of 10 gallons of water per acre by ground equipment.
BCBOA	Bollworm (including eggs)	0.12-0.24 lb/A (95-97% SC/S)	Use limited to cotton growing states other than AZ and CA. Foliar application. Repeat at 3 to 5 day intervals when moth flights begin and/or when eggs appear. Continue as long as eggs are present. Apply the low rate when pest populations are low or egg deposition is just starting.
BCBNA	Tobacco budworm (including eggs)	0.24 lb/A (95-97% SC/S)	
BCBOA	Bollworm (including eggs)	0.12-0.24 lb/A (95-97% SC/S)	Use of the dosage range is limited to cotton growing states other than AZ and CA. Use of the high rate is limited to AZ and CA. Foliar application. Apply on a 3 to 5 day schedule when larvae reach economic levels. Continue applications as long as eggs and larvae are present. Apply as a tank mix with other insecticides when egg hatch occurs because of delayed application or other causes, or when it is necessary to begin application in a field where the target or other pests have reached economic levels. Tank mix with Bacillus thuringiensis, dimethoate, dicrotophos, methyl parathion, azinphosmethyl, monocrotophos, chlorpyrifos, phosmet, methomyl, methidathion, acephate, polyhedral inclusion bodies of Heli-
BCBNA	Tobacco budworm (including eggs)		

CHLORDIMEFORM HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
			othis nuclear polyhedrosis virus, diflubenzuron, fenvalerate, permethrin, profenofos, sulprofos, methyl parathion plus EPN, and methyl parathion plus toxaphene.
		0.12-0.24 lb/A [with 40 in. row spacing and 20 in. band width] or [with 38 in. row spacing and 19 in. band width] (97% SC/S)	Foliar application (band). Apply when cotton is small enough to be fully covered by band.
PZZZZZA	Increase yield	0.12-0.24 lb/A (95-97% SC/S)	Increase yield. Foliar application. Apply as a broadcast spray. Apply 4 to 6 times at 5-7 day intervals beginning at first pinhead square formation (5 to 7 true leaf stage). Yield increase however, may not occur if plants are under stress during treatment.

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application		
	--		Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton
9900300 AAAAAAA	Tank Mix		
	--		Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton

CHLORDIMEFORM HYDROCHLORIDE

Listing of Registered Pesticide Products by Formulation

5.0001 95% technical chemical
chlordimeform hydrochloride (059702)
000100-00562

7.0001 97% technical chemical
chlordimeform hydrochloride (059702)
002139-00113

5.0015 95% soluble concentrate/solid
chlordimeform hydrochloride (059702)
000100-00554

7.0015 97% soluble concentrate/solid
chlordimeform hydrochloride (059702)
000279-02848

9999 State Label Registrations

AZ Reg. No.
002139-04323 002139-04357

CA Reg. No.
000100-04280 002139-04332 002139-04336 002139-04351

ID Reg. No.
002139-04349

NV Reg. No.
002139-04347

OR Reg. No.
002139-04335 002139-04350 002139-04353 002139-04360

WA Reg. No.
002139-04334 002139-04348 002139-04354 002139-04358

CHLORDIMEFORM HYDROCHLORIDE

Appendix A

Listing of Common Chemical Names Used on the Entry

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
035201	dicrotophos (ISO)	dimethyl phosphate ester with 3-hydroxy-N,N-dimethyl-cis-crotonamide
041801	EPN	O-ethyl O-(p-nitrophenyl)phenyl-phosphonothioate
053501	methyl parathion	O,O-dimethyl O-p-nitrophenyl phosphoro-thioate
058001	azinphosmethyl (ISO)	O,O-dimethyl S-[(4-oxo-1,2,3-benzo-triazin-3(4H)-yl)methyl] phosphoro- dithioate
058901	monocrotophos (ISO)	dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide
059201	phosmet (BSI)	N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate
109301	fenvalerate (ISO)	cyano(3-phenoxyphenyl)methyl 4-chloro-alpha-(1-methylethyl)benzeneacetate
111501	sulprofos	O-ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate

CHLORDIMEFORM HYDROCHLORIDE

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number

TERRESTRIAL FOOD CROP

(Agricultural Crops)

28007AA Cotton
TBCBOA Bollworm (including eggs)
ZZZZZA Increase yield
TBCBNA Tobacco budworm (including eggs)
(95% SC/S)
000100-00554

(97% SC/S)
000279-02848

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)."

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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.

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to all 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.

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 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, IV-5, and IV-6 to determine the storage and 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 sole 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 (See Tables B).

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 (name of pesticide) 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 (name of pesticide) 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), if applicable (if Table C lists required product-specific data).

c. Two copies of any required product-specific data, if applicable (if Table C lists 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. 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.

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

Guide to Use of This Bibliography

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

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

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

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

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

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

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

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

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

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

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

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

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OMB Approval No. 2000-0468 (Expires 12-31-8

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 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 ma 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) abc have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly info me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statem 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				

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.