REREGISTRATION ELIGIBILITY DOCUMENT
SODIUM AND CALCIUM HYPOCHLORITE SALTS

LIST A

CASE 0029

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ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS CONT'D

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

Executive Summary

The Environmental Protection Agency (referred to as "the Agency") first registered sodium and calcium hypochlorites as chlorinated inorganic disinfectants for use as sanitizers and disinfectants of surfaces, as disinfectants of water, and as chemicals to control microorganisms on certain foods and in certain industrial processes. All products which contain sodium and calcium hypochlorite as an active ingredient are eligible for reregistration except the uses on sugar syrup and raw sugar (the processed commodity). The uses on sugar syrup and raw sugar (the processed commodity) for calcium hypochlorite as well as for sodium hypochlorite are not eligible for reregistration without the acquiring of a food additive regulation from FDA.

In February 1986, the Agency issued a registration standard entitled "Guidance for the Reregistration of Pesticide Products Containing As the Active Ingredient Sodium and Calcium Hypochlorite Salts" (NTIS PB87-103222). The Registration Standard summarized the available data supporting the registration of sodium and calcium hypochlorite and determined that the data base was complete. No additional data were required for the generic data base in the 1986 Standard. The requirements listed in the Standard were cited only for those applicants who wanted to develop their own supporting data rather than rely upon and offer to pay compensation for the data cited in the Standard.

Recently, the Agency conducted a thorough review of the scientific data base and all relevant information supporting the reregistration of sodium and calcium hypochlorite and has determined that the data base is complete and is sufficient to allow the Agency to conduct a reasonable risk assessment. No further generic data are required. The data available to the Agency support the conclusion that the currently registered uses of sodium and calcium hypochlorites will not result in unreasonable adverse effects to the environment. No tolerances are required by the Agency to support the existing uses for the registered products because sodium hypochlorite is listed as GRAS (40 CFR 180.2) and calcium hypochlorite is exempt for the requirement of a tolerance under FFDCA sec. 408 (40 CFR 180.1054). It should be noted, however, that even though sodium hypochlorite is listed as GRAS (40 CFR 180.2) and calcium hypochlorite is exempt under Section 408 of the FFDCA from the requirements of a tolerance for use preharvest or postharvest on raw agricultural commodities, these exemptions do not cover the uses of sodium and calcium hypochlorite as food additives in or on processed foods which is regulated under Section 409 of the FFDCA. The 1986 Standard required registrants to obtain a food additive regulation for calcium hypochlorite in sugar syrup and raw sugar (the processed commodity) from FDA within 12 months from the date of issuance of the Standard or delete the claim from the appropriate product labeling. Since this regulation was not obtained, these uses must be deleted from the appropriate calcium,

as well as sodium hypochlorite product labeling within 8 months of the date of this document or be subject to enforcement action.

Accordingly, the Agency has determined that all products containing sodium and calcium hypochlorites as the active ingredient are eligible for reregistration except the uses on sugar syrup and raw sugar (the processed commodity) and will be reregistered when appropriate labeling and/or product specific data are submitted and/or cited. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

Section 4 (g) (2) (A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration of sodium and calcium hypochlorite. The document consists of five sections. Section I is this introduction. Section II describes sodium and calcium hypochlorite, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration decision for sodium and calcium hypochlorite and Section V discusses product reregistration. Additional details concerning the Agency's review of available data are available on request.[1]

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[1] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401, M St., S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENT COVERED BY THIS REREGISTRATION DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

The following active ingredients are covered by this Reregistration Eligibility Document:

Chemical Name: Sodium Hypochlorite

CAS Number: 7681-52-9

Office of Pesticide Programs Chemical Code Number: 014703

Empirical Formula: NaOCl

Chemical Name: Calcium Hypochlorite

CAS Number: 7778-54-3

Office of Pesticide Programs Chemical Code Number: 014701

Empirical Formula: CaOCl2

B. USE PROFILE

Type of Pesticide: Chlorinated Inorganic Disinfectants

Pests Controlled: Bacteria, fungi, and slime forming algae that are pathogenic to man and animals

Registered Use Groups: (See Appendix A for detailed specific use sites).

For Sodium Hypochlorite:
Terrestrial Food Crop: citrus, apples, pears, quinces, stone fruits, cherries, nectarines, peaches, pecans, plums/prunes, melons, cucumbers, peppers, pimentos, tomatoes(postharvest application/seed treatment), brussels sprouts, cabbage, cauliflower, artichokes, lettuce, carrots, potatoes, radishes, sweetpotatoes, asparagas, mushrooms, onions, celery, peppers (seed treatment)

Terrestrial Feed Crop: citrus, apples, tomatoes (postharvest application/seed treatment)
Terrestrial Non-Food
Aquatic Food Crop
Aquatic Non-Food Residential

Aquatic Non-Food Outdoor
Aquatic Non-Food Industrial
Indoor Food
Indoor Non-Food
Indoor Residential
Indoor Medical
Residential Outdoor

For Calcium Hypochlorite
Terrestrial Food Crop: pecans (water treatment), pecan (postharvest application to non-stored commodities), pimentos (seed treatment),tomatoes (seed treatment), potatoes and sweet potatoes (postharvest application to non-stored commodities), mushrooms (foliar or soil treatment), vegetables or post harvest application to vegetables crops, fruit or post harvest application to fruit crops, seeds (Agricultural),
Terrestrial Feed Crop: seeds (Agricultural)
Terrestrial Non-Food Crop
Aquatic Food Crop
Aquatic Non-Food Industrial
Aquatic Non-Food Residential
Aquatic Non-Food Outdoor
Indoor Food
Indoor Non-Food
Indoor Residential
Indoor Medical
Residential Outdoor

Formulation Types Registered:

For Sodium Hypochlorite: Formulation intermediate, granular, wettable powder, emulsifiable concentrate, soluble concentrate, solution-ready to use.

For Calcium Hypochlorite: Formulation intermediate, dust, granular, pelletted/tabletted, wettable powder, wettable powder/dust, soluble concentrate, solution-ready to use.

C. REGULATORY HISTORY

Sodium and calcium hypochlorites are well known compounds whose chemical and toxicological properties are extensively documented in published literature and studies submitted to the Agency. In February 1986, a Registration Standard was issued for sodium and calcium

hypochlorite which summarized the available data supporting their registration. The standard concluded that no additional scientific data would be necessary to support the registration or reregistration of products which contain sodium hypochlorite from 5.25% to 12.5% or calcium hypochlorite from 65% to 70% as the only active ingredient, provided that no inert ingredients other than water were added and that Toxicity Category I labeling is used. The Registration Standard provided various options to applicants who wanted to register or reregister sodium or calcium hypochlorite products. The options implemented were:

1) Option I: Reliance on available data to support registration of toxicity category I products and adopt the generic labeling provided by the Agency. (This option was the "general registration" procedure designed to reduce processing time and costs to the Agency and registrants, while continuing to assure human and environmental protection. Only products containing 5.25%, 9.2%, 10%, or 12.5% sodium hypochlorite, or 65% calcium hypochlorite as the sole active ingredients were eligible for this option).

2) Option II: Either reliance on available data to support registration of toxicity category I products and submit their own labeling or development of data independently to support registration of toxicity category I products and submit their own specific labeling;

3) Option III: Development of product specific data independently by registrants to support lower toxicity categories II, III, or IV.

Manufacturing-use sodium hypochlorite and calcium hypochlorite products were defined by the standard as 12.5% and 65%, respectively; and product chemistry and acute toxicity data developed with these formulations also could be used to support end-use products of the same concentrations. The product chemistry and acute toxicity data developed with these formulations would also be extrapolated to support end-use concentrations of sodium hypochlorite down to 5.25%, since they are simply aqueous dilutions of the 12.5% manufacturing-use product.

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

The Agency has conducted a thorough review of the scientific data base for sodium and calcium hypochlorite. Based on the evaluation of these data, the Agency has no reason to change the major findings made in the 1986 document "Guidance for the Reregistration of Pesticide Products Containing as the Active Ingredient Sodium and Calcium Hypochlorite Salts". These findings are summarized below:

A. PRODUCT IDENTIFICATION

In the 1986 Registration Standard, no additional data were required on the product chemistry of sodium or calcium hypochlorite. The product chemistry data requirements listed in the standard were listed only for those applicants who wished to develop their own data rather than rely upon and offer to pay compensation for data cited in the standard. Calcium hypochlorite is a dull white powder with a strong odor of chlorine. It is a strong oxidant and has a critical ignition temperature of about 75° C. It decomposes violently above 150° C. This chemical has a molecular weight of 142.99. Sodium hypochlorite is produced as a greenish-yellow liquid with the smell of chlorine. It is inherently unstable and its decomposition is hastened principally by light, heat and trace metals. It is moderately corrosive and specific packaging is essential. Sodium hypochlorite is a strong oxidizing agent. This chemical has a molecular weight of 74.44 (anhydrous). The Agency has reevaluated the product chemistry data base and has determined that no additional data are required for reregistration for products that were subject to the standard.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Data Base

All current toxicological data requirements are satisfied. No further data were required in the 1986 registration standard (provided that toxicity category I labeling was used). The Agency has reevaluated the scientific data base for sodium and calcium hypochlorite and finds that the database for the purpose of human risk assessment is complete and no additional data are required. The available acute toxicity data are sufficient to address the acute toxicity risk to humans and the Agency has concluded that toxicity category I labeling is appropriate due to sodium and calcium hypochlorite's known potential for causing damage to

eyes. The Agency also concludes that no subchronic or chronic studies are needed. This conclusion is based on the simple chemical nature and structure of sodium and calcium hypochlorites and their high oxidative reactivity with organic matter which converts them readily into sodium chloride and calcium chloride. The human health concerns relative to these inorganic ions are well understood and the use of these chemicals will not add any additional calcium or sodium chloride burden for the users.

The Agency is aware of the potential risk concerning the formation of trihalomethanes, especially in drinking water, from the use of sodium and calcium hypochlorite. The Office of Drinking Water has addressed this risk by setting a maximum contaminant level of 100 ppb for trihalomethanes in drinking water. The Agency believes that this level is commensurate with an acceptable risk determination and limits the dietary exposure to hypochlorites.

2. Dietary Exposure

a. Residue Data

The February 1986 Guidance Document listed no residue chemistry data requirements for calcium or sodium hypochlorite. Under 40 CFR 180.1054, calcium hypochlorite is exempted from the requirement of a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities. Sodium hypochlorite is considered to be Generally Recognized As Safe (GRAS) under 40 CFR 180.2. (The Agency intends to propose a specific exemption from the requirement of a tolerance for sodium hypochlorite on all raw agricultural commodities (RAC) under FFDCA sec. 408, and to delete the GRAS listing from 180.2). Based on this, no residue chemistry data are required for sodium or calcium hypochlorite under current scientific standards. There are no minor use concerns at present and there are no codex, Mexican, or Canadian MRL considerations with respect to sodium or calcium hypochlorite.

b. Tolerance Reassessment

Sodium hypochlorite is considered to be GRAS under 40 CFR 180.2. The Agency intends to propose a specific exemption from the requirement of a tolerance for sodium hypochlorite on all raw agricultural commodities (RAC) under FFDCA sec. 408, and to delete the GRAS listing from 180.2. An incidental food additive regulation allowing the use of sodium hypochlorite as a terminal sanitizing rinse on food processing equipment has been established (21 CFR 178.1010). Also, a food additive regulation permitting the use of sodium hypochlorite in washing or assisting in lye peeling of fruits and vegetables has been established (21 CFR 173.315) by the Food and Drug Administration (FDA). No new tolerances are necessary for the existing uses of sodium hypochlorite.

Calcium hypochlorite is exempted from the requirement of a tolerance under FFDCA sec. 408 (40 CFR 180.1054) when used preharvest or postharvest in solution on all raw agricultural commodities. The Agency has reevaluated this exemption and has determined that it is still appropriate. Also, an incidental food additive regulation allowing the use of calcium hypochlorite as a terminal sanitizing rinse on food processing equipment has been established (21 CFR 178.1010).

It should be noted, however, that even though sodium hypochlorite is considered to be GRAS and calcium hypochlorite is exempt under Section 408 of the FFDCA from the requirements of a tolerance for use preharvest or postharvest on raw agricultural commodities, these exemptions do not cover the uses of sodium and calcium hypochlorite as food additives in or on processed foods, which is regulated under Section 409 of the FFDCA. The 1986 Standard required registrants to obtain a food additive regulation for calcium hypochlorite in sugar syrup and raw sugar (the processed commodity) from FDA within 12 months from the date of issuance of the Standard or delete the claim from the appropriate product labeling. This food additive regulation has not been established for either sodium or calcium hypochlorite.

3. Occupational and Residential Exposure

The 1986 Guidance Document for sodium and calcium hypochlorite did not require reentry or

mixer/loader/applicator exposure monitoring data. Sodium and calcium hypochlorite are chlorinated inorganic disinfectants registered for use in laundry, swimming pools, ponds, drinking water, and other water and wastewater systems, on food and non-food contact surfaces, and on various crops, including mushrooms (pins), potatoes, and sweet potatoes (postharvest). Based on current registered use patterns, the Agency has determined that the potential for post application exposure for sodium and calcium hypochlorite is minimal and therefore does not meet the Agency's exposure criteria for requirement of reentry or mixer/loader/applicator exposure monitoring data. Therefore, these data are not required to support the reregistration of sodium and calcium hypochlorite.

Based on the acute toxicity of sodium and calcium hypochlorite, label requirements for the use of protective clothing, including safety glasses or goggles and chemical-resistant gloves while handling end-use products containing sodium or calcium hypochlorite as the active ingredient remain as required in the 1986 Guidance Document. Reentry levels for application of sodium or calcium hypochlorite to swimming pools (3.0 ppm) and spas/hot tubs (5.0 ppm) and reentry intervals for spray/fog application to food and non-food contact surfaces (2 hour reentry interval following application) also remain as required in the 1986 Guidance Document.

4. Risk Assessment

Based on the above considerations concerning the toxicology profile and exposure scenarios for calcium and sodium hypochlorites it can be concluded that risks from chronic and subchronic exposure to low levels of calcium and sodium hypochlorites are minimal and without consequence on human health. Risks for acute exposure to high concentrations of calcium and sodium hypochlorites may be significant with respect to eye and skin injury but the Agency believes that these risks are sufficiently mitigated by adequate precautionary labeling requiring protection of eyes and skin while using calcium and sodium hypochlorites.

C. ENVIRONMENTAL ASSESSMENT

The environmental fate and ecological effects data requirements have been satisfied for all currently registered uses eligible for reregistration. In the 1986 Registration Standard, it was determined that the available fish and wildlife data were sufficient to characterize the acute toxicity risks to non-target

organisms and that no subchronic or chronic data were required. Many of these data requirements were fulfilled by the EPA Publication Ambient Water Quality Criteria for Chlorine by J. Tobler, et al; U.S. EPA, June 1981. Thus, no further environmental fate or ecological effects data were required.

The data cited in the Standard are discussed below. Upon reevaluation, the available data support the conclusion that the currently registered uses of sodium and calcium hypochlorite will not result in unreasonable adverse effects to the environment. As discussed in the Standard, the currently accepted uses that result in point source discharges of effluents containing sodium and calcium hypochlorites will continue to be regulated through issuance of National Pollutant Discharge Elimination System (NPDES) permits. Such permits are tailored to a specific site or point of discharge. The Agency has determined that the discharge amounts permitted by the NPDES permits, which are specific to each site, will not pose significant adverse effects on non-target organisms.

1. Ecological Effects Assessment

There are a number of scientifically sound data considered adequate to characterize the toxicity of the sodium and calcium hypochlorite salts. Results from the avian acute oral studies (MRID 00007276, 00007403, and 00007496) indicate that the sodium and calcium salts are low in toxicity to avian wildlife. The results from the avian subacute dietary studies (MRID 00007275, 00007278, 00007404, and 00007405) indicate that the sodium salt is practically non-toxic to upland game birds and waterfowl. Results from the fish acute toxicity studies (MRID 00007400, 00007495, 00008190, 00008191, and 00007401) indicate that the hypochlorite salts are highly toxic to freshwater fish. The acceptable studies on the acute toxicity to freshwater invertebrates (MRID 00007279, 00007402, 00007495, and 00019313) indicate that the hypochlorite salts are very highly toxic to freshwater invertebrates. Although these fish and aquatic invertebrate studies demonstrate high toxicity to sodium and calcium hypochlorite, the Agency believes that these risks are sufficiently mitigated by adequate precautionary labeling and the NDPES permit requirement. The results of these studies are listed below:

Species	Test	Value	Toxicity
Upland Game Birds	acute oral	LD_{50} 3474 mg/kg (Ca) LD_{50} >2510 mg/kg (Na)	Practically Non-toxic
Upland Game Birds and Waterfowl	Subacute Dietary	LC_{50} >5000 ppm (Na)	Practically Non-toxic
Cold Water Fish	acute toxicity	LC_{50} 0.132-1.35 ppm (96-hr) (hypochlorite salts)	Highly toxic freshwater fish
Warm Water Fish	acute toxicity	LC_{50} 0.28-2.1 ppm (96-hr) (hypochlorite salts)	Highly toxic freshwater fish
Daphnia magna	acute toxicity	LC_{50} 0.037-2.3 ppm (48-hr) (hypochlorite salts)	Very highly toxic to freshwater invertebrate

2. Environmental Fate Assessment

The February 1986 Guidance Document listed no environmental fate deficiencies for calcium or sodium hypochlorite. The environmental fate data requirements for the hypochlorite salts have been fulfilled by the document Ambient Water Quality Criteria for Chlorine (MRID 40911802), published by the Environmental Protection Agency. No further environmental fate data were required in the 1986 Guidance Document. After reevaluating the environmental fate data base, the Agency has determined that it will not require any additional environmental fate data. In aqueous media, sodium hypochlorite and calcium hypochlorite produce hypochlorous acid, hypochlorite ions, and hydronium ions, a reaction which is independent of the nature of the counter cation (i.e., sodium or calcium). The amount of hypochlorous acid, hypochlorite and hydronium ions present in solution depends on the pH of the medium. The data available indicate that the photolysis rate of calcium hypochlorite in aqueous solution increases with increasing light intensity. Calcium hypochlorite at 10 g/l has a half-life of 10-12 months and 4 months under diffused daylight and under diffused daylight with

intermittent direct sunlight, respectively. Seawater has a large capacity to consume hypochlorites. Sodium hypochlorite is expected to show a similar behavior. When sodium hypochlorite is added to seawater, residual chlorine levels declined rapidly in the first hour. The rapid initial decline was followed by a much slower and continuous decline in residual chlorine levels. The available data indicate that hypochlorites undergo reaction with bromide ions in seawater to form hypobromite. This reaction is rapid and appears to be complete within 2.5 minutes. Although hypobromite is acutely toxic to aquatic organisms, from a chronic viewpoint it does not appear to be toxic because it is highly volatile and will not persist in the aquatic environment. (Halflife is less than 96 hrs in water). The Agency believes that the risk of acute exposure to aquatic organisms is sufficiently mitigated by adequate precautionary labeling and the NDPES permit requirement.

Although no exposure, bioaccumulation, or volatility data are available to quantitatively assess the potential for exposure of wildlife to the hypochlorites, the use patterns indicate that most exposure will occur in the aquatic environment, and that significant amounts of hypochlorites in the terrestrial environment will not occur.

The available data are considered sufficient to assess the environmental fate of the hypochlorite salts and the data support the conclusion that the-currently registered uses of sodium and calcium hypochlorite will not result in unreasonable adverse effects to the environment.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

Section 4 (g) (2) (A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing sodium or calcium hypochlorite as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing sodium or calcium hypochlorite. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium and calcium hypochlorites, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B are sufficient to allow the Agency to conduct a reasonable risk assessment for the registered uses of sodium and calcium hypochlorite. The data available to the Agency support the conclusion that the registered uses of sodium and calcium hypochlorite will not result in unreasonable adverse effects to the environment. The Agency has determined that all products containing sodium and calcium hypochlorites as the active ingredient are eligible for reregistration except the uses on sugar syrup and raw sugar (the processed commodity). The uses on sugar syrup and raw sugar (the processed commodity) for sodium and calcium hypochlorite are not eligible for reregistration without the acquiring of a food additive regulation from FDA. (See Section III(B)(2)(b) of this document). Since this regulation was not obtained, these uses must be deleted from the appropriate product labeling within 8 months of the date of this document or be subject to enforcement action. The reregistration of particular products is addressed in section V of this document ("Product Registration").

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix B. Although the Agency has found that products containing sodium and calcium hypochlorite are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support reregistration of products containing sodium or calcium hypochlorite, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for

generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing sodium or calcium hypochlorites has been reviewed and determined to be complete for reregistration. No further generic data are required.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM OR CALCIUM HYPOCHLORITES

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling. Any product label which allows both manufacturing and end use must be amended to specify <u>only</u> manufacturing <u>or</u> end use. In this situation, if a registrant amends his/her label to specify manufacturing use only and wishes to retain end use registration, he/she must apply for a separate end-use product registration.

2. Based on the reviews of the generic data, the following additional label statements are required:

   a. In the directions for use, the following statement must appear:

      "Formulators using this product are responsible for obtaining EPA registration of their formulated products."

   b. In the directions for use, the following statement regarding acceptable use patterns must appear:

      "For formulation into end-use products intended only for (<u>list acceptable sites</u>).

   c. The following Environmental Hazard statement is required for any use that results in discharge into the aquatic environment:

      "This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously

notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

d. Because of the corrosive nature of sodium and calcium hypochlorite and the potential for severe eye and skin damage from accidental spills of these chemicals, **EPA is requiring that the Statement of Practical Treatment appear on the front panel of all products which have been assigned toxicity category I for eye and/or skin effects.**

e. The "If Swallowed" statement in the statement of practical treatment must read as follows:

"IF SWALLOWED, drink large amounts of water. DO NOT induce vomiting. Call a physician or poison control center immediately."

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredients, sodium and calcium hypochlorites, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(b) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data when they have been submitted and/or cited and determine whether to reregister individual products.

For products that meet the criteria of the 1986 standard and were registered or reregistered under option I (the "general Registration" procedure) (the registrant relied on available data to support registration of Toxicity Category I products and adopted the generic labeling provided by the Agency), or option II (the registrant either relied on available data to support registration of Toxicity Category I products and submitted their own specific labeling or developed data independently to support registration of toxicity category I products and submitted their own specific labeling) , **the Agency is requiring that labels reflecting the changes stated within this document and CSFs be submitted within 8 months of receipt of this document.** Upon receipt and approval of revised labels and CSFs, these products, will be reregistered under section 4(g).

For products that do not meet the criteria of the 1986 Standard, (i.e. products whose concentrations of the a.i. fall outside the range specified by the standard for sodium hypochlorite 5.25% - 12.5% and for calcium hypochlorite 65% - 70%; products with intentionally added inert ingredients other than water; and products which are mixtures with other active ingredients), **the Agency is requiring that the registrants either submit product specific data or cite previously submitted data to support their registrations and submit revised labeling and CFSs within 8 months of receipt of this document before the products will be considered for reregistration.** After reviewing these data and the revised labels, the Agency will determine whether to reregister each product based on whether or not it meets the requirements in section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

While the Agency will continue to register sodium and calcium hypochlorite products as discussed above under the provisions of the February 1986 Registration Standard, EPA does not plan to issue further amendments to that document. Consequently, EPA will no longer consider amendments to general registration (Series 20,000) labeling for the purpose of adding uses or language inconsistent with that Standard. Applicants who wish approval for such amendments must apply for a new product registration and will be assigned a conventional registration number upon acceptance.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are stated in the attached appendices. For those products that were not subject to the 1986 Registration Standard (which include those products whose concentrations of the a.i. fall outside the range covered by the standard for sodium hypochlorite 5.25% - 12.5% and for calcium hypochlorite 65% - 70%; those products with additional inert ingredients other than water, and those products which are mixtures with other active ingredients) the registrant is responsible for either submitting data or citing previous data he submitted to support his registrations. Registrants of products which were subject to the 1986 registration standard do not need to submit or cite data since they did so already in complying with that standard.

The Agency has decided to continue its current policy of waiving the product-by-product efficacy data requirement normally levied on sanitizers and disinfectants for sodium and calcium hypochlorite formulations. The Agency has concluded that the published literature data can reasonably be extrapolated to the full range of these products.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING SODIUM OR CALCIUM HYPOCHLORITE

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling. Any product label which allows both manufacturing and end use must be amended to specify <u>only</u> manufacturing <u>or</u> end use. In this situation, if a registrant amends his label to specify end-use registration and wishes to retain manufacturing use registration, he must apply for a separate manufacturing use product registration.

2. Because of the corrosive nature of sodium and calcium hypochlorite and the potential for severe eye and skin damage from accidental spills of these chemicals, **EPA is requiring that the Statement of Practical Treatment appear on the front panel of all products which have been assigned toxicity category I for eye and/or skin effects.**

3. The "If Swallowed" statement must read as follows:

   "IF SWALLOWED, drink large amounts of water. DO NOT induce vomiting. Call a physician or poison control center immediately."

4. The 1986 Registration Standard stated that applicants whose product labeling contains use in sugar syrup and raw sugar must obtain a food additive regulation to support these uses as required by the provisions of the Federal Food Drug and Cosmetic Act (21 CFR 173 Subpart D -Specific Usage Additives). Since this regulation was not obtained, registrants whose product labeling contains the food additive claim for calcium hypochlorite in sugar syrup and raw sugar (the processed commodity) must delete this claim from the appropriate calcium, as well as sodium hypochlorite labeling within 8 months of the date

of this document or be subject to enforcement action.

5. The following Environmental Hazard statement is required for any use that results in discharge into the aquatic environment:

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

APPENDIX A

DETAILED SPECIFIC USE SITES FOR SODIUM AND CALCIUM HYPOCHLORITES

CALCIUM HYPOCHLORITE (014701)

SITES (APPLICATION TYPE-IF GIVEN)	USE GROUPS
PECANS (WATER TREATMENT)	TERRESTRIAL FOOD CROP
PECANS (POSTHARVEST APP TO NON-STRD COMM.)	TERRESTRIAL FOOD CROP
TOMATOES (SEED TREATMENT)	TERRESTRIAL FOOD CROP
POTATOES (POSTHRT. APP. TO NON-STRD COMM.)	TERRESTRIAL FOOD CROP
SWEET POTATOES (POSTHRT. TO NON-STRD. CM.)	TERRESTRIAL FOOD CROP
MUSHROOMS (FOLIAR OR SOIL TRT.)	TERRESTRIAL FOOD CROP
PIMENTOS (SEED TREATMENT)	TERRESTRIAL FOOD CROP
VEGETABLES OR POST HRT. APP TO VEG. CROPS	TERRESTRIAL FOOD CROP
FRUIT OR POST HRT. APP TO FRUIT CROPS	TERRESTRIAL FOOD CROP
SEEDS- AGRICULTURAL	TERRESTRIAL FOOD CROP
"	TERRESTRIAL FEED CROP
SEEDS-ORNAMENTAL	TERRES. NON-FOOD CROP
SUGAR-RAW	INDOOR FOOD
FISH-EXCLUDING SHELLFISH	AQUATIC FOOD CROP
POULTRY HOUSE TRT.	INDOOR FOOD
POULTRY FEEDING AND WATERING EQPMT	INDOOR FOOD
POULTRY TRANSPORTATION VEHICLES	INDOOR FOOD
ANIMAL EQUIPMENT	INDOOR FOOD
ANIMAL EQUIPMENT	INDOOR NON-FOOD
ANIMAL EQUIPMENT	INDOOR RESIDENTIAL
ANIMAL FEEDING/WATERING EQUIPMENT	INDOOR NON-FOOD
ANIMAL FEEDING/WATERING EQUIPMENT	INDOOR FOOD
ANIMAL FEEDING/WATERING EQUIPMENT	INDOOR RESIDENTIAL
ANIMAL LIVING QTRS AND TRANS VEHICLES	INDOOR FOOD
"	INDOOR NON-FOOD
"	INDOOR RESIDENTIAL
COMMERCIAL EGG TRT	INDOOR FOOD
DAIRY UTIL. AND MILKING EQUIPMENT	INDOOR FOOD
DAIRIES	INDOOR FOOD
FARM PREMISES (UNSPECIFIED)	INDOOR FOOD
FARM OR AGRICULTURAL STRUCTURES AND EQUIP.	INDOOR FOOD
FOOD MARKET/STRG/DISTRIBUTION FACILITIES	INDOOR FOOD
BEEKEEPING EQUIPMENT	INDOOR FOOD
FISH HANDLING EQUIP.	AQUATIC FOOD CROP
FISH POND EQUIPMENT	AQUATIC FOOD CROP
HOUSEHOLD PREMISES	INDOOR RESIDENTIAL
SIDING	OUTDOOR RESIDENTIAL
FISH HATCHERIES AND PONDS	AQUATIC FOOD CROP
LOBSTER AND OYSTER PONDS	AQUATIC FOOD CROP
FISH/FOOD PROCESSING WATER	INDOOR FOOD
FRUIT/VEGETABLE PROCESSING/WASH WATER	INDOOR FOOD
CANNERY COOLING CANAL WATER	INDOOR FOOD

PULP AND PAPER MILL SYSTEMS	AQUATIC NON-FOOD INDUS.
POULTRY DRINKING WATER	INDOOR FOOD
SWIMMING POOL WATER	AQUATIC NON-FOOD RESID.
SPAS AND HOT TUBS-OUTDOOR	AQUATIC NON-FOOD RESID.
ANIMAL/HUMAN DRINKING WATER AND SURFACES	INDOOR FOOD
AIR WASHER WATER	AQUATIC NON-FOOD INDUS.
COOLING TOWER WATER	AQUATIC NON-FOOD INDUS.
EVAPORATIVE CONDENSER WATER	AQUATIC NON-FOOD INDUS.
PONDS-ORNAMENTAL AND FISH	AQUATIC NON-FOOD RESID.
SEWAGE SYSTEMS/WASTE WATER\SEPTIC TANKS	AQUATIC NON-FOOD INDUS.
HEAT EXCHANGER/INDUSTRIAL PROCESSING H2O	AQUATIC NON-FOOD INDUS.
WHIRLPOOL BATH WATER	AQUATIC NON-FOOD RESID.
RESERVOIRS	AQUATIC FOOD CROP
BOATS AND SHIPS	AQUATIC NON-FOOD OUTDOOR
ARTIFICAL SAND BEACHES	AQUATIC NON-FOOD RES
RECREATIONAL VEHICLES	INDOOR NON-FOOD
FOOD PROCESSING EQUIP.	INDOOR FOOD
FOOD PROCESSING PREMISES	INDOOR NON-FOOD
BAKERY PROCESSING EQUIP.	INDOOR FOOD
BAKERY PROCESSING PREMISES	INDOOR NON-FOOD
BOTTLING PROCESSING EQUIP.	INDOOR FOOD
BOTTLING PREMISES	INDOOR NON-FOOD
BREWERY PROCESSING EQUIP.	INDOOR FOOD
BREWERY PREMISES	INDOOR NON-FOOD
CANNERY PROCESSING EQUIP.	INDOOR FOOD
CANNERY PROCESSING PREMISES	INDOOR NON-FOOD
ICE CREAM PROCESSING EQUIP.	INDOOR FOOD
BUTTER PROCESSING EQUIP.	INDOOR FOOD
MILK PROCESSING EQUIP.	INDOOR FOOD
MILK PROCESSING PREMISES	INDOOR NON-FOOD
CHEESE AGING ROOMS	INDOOR FOOD
CHEESE PROCESSING PREMISES	INDOOR NON-FOOD
MEAT PROCESSING EQUIP.	INDOOR FOOD
MEAT PROCESSING PREMISES	INDOOR NON-FOOD
POULTRY PROCESSING EQUIP.	INDOOR FOOD
POULTRY PROCESSING PREMISES	INDOOR NON-FOOD
WINERY EQUIP.	INDOOR FOOD
WINERY PREMISES	INDOOR NON-FOOD
EGG BREAKING EQUIP.	INDOOR FOOD
BEVERAGE PROCESSING EQUIP.	INDOOR FOOD
BEVERAGE PROCESSING PREMISES	INDOOR NON-FOOD
FISH PROCESSING EQUIP.	INDOOR FOOD
EATING ESTAB./EQUIP./UTENSILS/CONTACT SURF	INDOOR FOOD
EATING ESTAB. NON-FOOD CONTACT SURFACES	INDOOR NON-FOOD
COMMERCIAL/INDUSTRIAL/STORAGE PREMISES	INDOOR NON-FOOD
GROUTS/AWNINGS	RESIDENTIAL OUTDOOR
LAUNDRY-HOUSEHOLD	INDOOR RESIDENTIAL
LAUNDRY-COMMERCIAL	INDOOR NON-FOOD
DOMESTIC DWELLINGS	INDOOR RESIDENTIAL
BATHROOM PREMISES/URINALS/TOILETS	INDOOR RESIDENTIAL
INDUSTRIAL PROCESS PLANT PREMISES	INDOOR NON-FOOD
INSTITUTIONAL PREMISES	INDOOR NON-FOOD

ENVIRONMENTAL INANIMATE HARD SURFACES	INDOOR MEDICAL
"	INDOOR RESIDENTIAL
HEMODIALYSIS MACHINES	INDOOR MEDICAL
HOSPITAL PREMISES	INDOOR MEDICAL
FURNITURE-OUTDOOR	RESIDENTIAL OUTDOOR
ROOFS	RESIDENTIAL OUTDOOR
SHOWER CURTAIN SURFACES	INDOOR NON-FOOD
TILE-CERAMIC/TILE SURFACES	INDOOR NON-FOOD
SURFACES-PAINTED OR UNPAINTED/FINSD WOOD	INDOOR NON-FOOD
"	RESIDENTIAL OUTDOOR
HARD NONPOROUS SURFACE	INDOOR NON-FOOD
"	INDOOR MEDICAL
"	INDOOR FOOD
ASPHALT ROOFS/ROOFS-WOOD	RESIDENTIAL OUTDOOR
AUTO TOPS	RESIDENTIAL OUTDOOR
WALL SURFACES/WALL-BRICK	INDOOR NON-FOOD
"	RESIDENTIAL OUTDOOR
ASBESTOS ROOFS/SHINGLES	RESIDENTIAL OUTDOOR

USE GROUP SUMMARY: TERRESTRIAL FOOD CROP, TERRESTRIAL FEED CROP, TERRESTRIAL NON-FOOD CROP, AQUATIC FOOD CROP, AQUATIC NON-FOOD OUTDOOR, AQUATIC NON-FOOD INDUSTRIAL, AQUATIC NON-FOOD RESIDENTIAL, RESIDENTIAL OUTDOOR, INDOOR FOOD, INDOOR NON-FOOD, INDOOR MEDICAL, INDOOR RESIDENTIAL.

SODIUM HYPOCHLORITE (14703)

SITES (APPLICATION TYPES-IF GIVEN)	USE GROUPS
CITRUS-INC. GRAPEFRUIT, ORANGES, LEMONS	TERRESTRIAL FOOD CROP
"	TERRESTRIAL FEED CROP
APPLES	TERRESTRIAL FOOD CROP
"	TERRESTRIAL FEED CROP
PEARS	TERRESTRIAL FOOD CROP
QUINCES	TERRESTRIAL FOOD CROP
STONE FRUITS	TERRESTRIAL FOOD CROP
CHERRIES	TERRESTRIAL FOOD CROP
NECTARINES	TERRESTRIAL FOOD CROP
PEACHES	TERRESTRIAL FOOD CROP
PLUMS/PRUNES	TERRESTRIAL FOOD CROP
MELONS	TERRESTRIAL FOOD CROP
CUCUMBERS	TERRESTRIAL FOOD CROP
PEPPERS	TERRESTRIAL FOOD CROP
PIMENTOS	TERRESTRIAL FOOD CROP
PECANS (POSTHARVEST APP TO NON-STRD COMM)	TERRESTRIAL FOOD
TOMATOES (POSTHARVEST APP./SEED TRT)	TERRESTRIAL FOOD CROP
CROP "	TERRESTRIAL FEED CROP
BRUSSEL SPROUTS	TERRESTRIAL FOOD CROP
CABBAGE	TERRESTRIAL FOOD CROP
CAULIFLOWER	TERRESTRIAL FOOD CROP
ARTICHOKES	TERRESTRIAL FOOD CROP
LETTUCE	TERRESTRIAL FOOD CROP
CARROTS	TERRESTRIAL FOOD CROP
POTATOES	TERRESTRIAL FOOD CROP
RADISHES	TERRESTRIAL FOOD CROP
SWEET POTATOES	TERRESTRIAL FOOD CROP
ASPARAGUS	TERRESTRIAL FOOD CROP
MUSHROOMS	TERRESTRIAL FOOD CROP
MUSHROOMS	GREENHOUSE FOOD CROP
ONIONS	TERRESTRIAL FOOD CROP
CELERY	TERRESTRIAL FOOD CROP
PEPPERS (SEED TRT)	TERRESTRIAL FOOD CROP
ROSES-CUTTINGS	TERRESTRIAL NON-FOOD C.
SUGAR-RAW	INDOOR FOOD
LIVESTOCK PENS/STALLS/FEEDING/WATER EQUIP.	INDOOR FOOD
FISH (MEAT)	INDOOR FOOD
POULTRY PREMISES/FEEDING/WATERING/TRANSPOR.	INDOOR FOOD
POULTRY (ANIMAL TREATMENT)	INDOOR FOOD
ANIMAL TRANSPORTATION VEHICLES/EQUIPMENT	INDOOR FOOD
ANIMAL TRANSPORTATION VEHICLES/EQUIPMENT	INDOOR NON-FOOD
WOOD SIDING (NONSOIL CONTACT NONFUM. TREAT)	OUTDOOR RESIDENTIAL
SUGARCANE JUICE	INDOOR FOOD
BUTTER PROCESSING EQUIPMENT	INDOOR FOOD
SEWAGE EFFLUENT WATER	AQUATIC NONFOOD INDUS

ANIMAL CAGES/LIVING QTRS/FEEDING/WATERING	INDOOR NON-FOOD
"	INDOOR FOOD
"	INDOOR RESIDENTIAL
PET SLEEPING QUARTERS	INDOOR NON-FOOD
COMMERCIAL EGG TRT	INDOOR FOOD
DAIRY PREMISES/EQUIP./STORAGE/UTENSILS	INDOOR FOOD
FARM/AGRICULTURAL EQUIP./BARN	INDOOR FOOD
BEEKEEPING EQUIP.	INDOOR FOOD
FISH HANDLING EQUIP.	AQUATIC FOOD CROP
FISH POND EQUIP.	AQUATIC FOOD CROP
BATH MATS	INDOOR RESIDENTIAL
HOUSEHOLD CONTENTS/PREMISES	INDOOR RESIDENTIAL
SICKROOM EQUIP./PREMISES/UTENSILS	INDOOR MEDICAL
SIDING/WOOD SIDING	RESIDENTIAL OUTDOOR
FISH HATCHERIES/PONDS	AQUATIC FOOD CROP
MARINE LOBSTER/OYSTER PONDS	AQUATIC FOOD CROP
BOTTLE WASHER WATER	INDOOR FOOD
BREWERY PASTEURIZER WATER	INDOOR NON-FOOD
EGG/FOOD PROCESSING WATER	INDOOR FOOD
MEAT/POULTRY/FRUIT/VEGETABLE PROCESSING H2O	INDOOR FOOD
INDUSTRIAL PULP AND PAPER MILL SYSTEMS	AQUATIC NON-FOOD
SWIMMING POOL WATER	AQUATIC NON-FOOD RES.
HOT TUBS/SPAS/ARTIFICIAL SAND BEACHES	AQUATIC NON-FOOD RES.
DRAINS/DRAIN PIPES	AQUATIC NON-FOOD RES.
HUMAN DRINKING WATER	INDOOR FOOD
ANIMAL DRINKING WATER	INDOOR NON-FOOD
COOLING TOWER/EVAPORATIVE CONDENSER WATER	AQUATIC NON-FOOD INDUS.
IRRIGATION SUPPLY SYSTEMS	AQUATIC FOOD CROP
PONDS-ORNAMENTAL FISH/FOUNTAINS	AQUATIC NON-FOOD RES.
SEWAGE SYSTEMS/WASTE WATER SYSTEMS	AQUATIC NON-FOOD INDUS.
DISHWASHING MACHINE WATER	AQUATIC NON-FOOD RES.
INDUSTRIAL PROCESSING WATER	AQUATIC NON-FOOD INDUS.
IMMERSION ULTRASONIC TANK WATER	AQUATIC NON-FOOD INDUS.
WHIRLPOOL BATH WATER	AQUATIC NON-FOOD RES.
PONDS	AQUATIC NON-FOOD OUTD.
RESERVOIRS	AQUATIC FOOD CROP
BOAT BOTTOMS/SHIP HULLS	AQUATIC NON-FOOD INDUS.
TRUCKS	INDOOR NON-FOOD
FOOD PROCESSING EQUIP.	INDOOR FOOD
FOOD PROCESSING PLANT PREMISES	INDOOR NON-FOOD
BAKERY PROCESSING EQUIP.	INDOOR FOOD
BAKERY PROCESSING PREMISES	INDOOR NON-FOOD
BOTTLES/BOTTLING PLANT SURFACES	INDOOR FOOD
BREWERY PROCESS PLANT EQUIP.	INDOOR FOOD
BREWERY PREMISES	INDOOR NON-FOOD
CANNERY PROCESS PLANT PREMISES/EQUIP.	INDOOR FOOD
MILK TRANSPORT. VEHICLES/PROCESS PLANT/EQUIP.	INDOOR FOOD
CHEESE PROCESSING EQUIP.	INDOOR FOOD
FRUIT PROCESSING EQUIP.	INDOOR FOOD
VEGETABLE PROCESSING PLANTS/EQUIP.	INDOOR FOOD
MEAT PACKING EQUIP./PROCESS PLANT PREMISES	INDOOR FOOD
POULTRY PROCESSING EQUIP./PLANT PREMISES	INDOOR FOOD

WINERY PROCESSING EQUIP./PROCESS PLANT	INDOOR FOOD
EGG PROCESSING PLANT/EQUIPMENT	INDOOR FOOD
BEVERAGE PROCESSING EQUIPMENT/CASES/PLANT	INDOOR FOOD
FISH PROCESSING PLANT PREMISE	INDOOR FOOD
EATING ESTABLISHMENT/UTENSILS/FD-CONTACT S.	INDOOR FOOD
FOOD HANDLING SURFACES/PREMISES/UTEN./EQUIP.	INDOOR FOOD
FOOD MARKETS	INDOOR FOOD
AMBULANCES	INDOOR MEDICAL
HOSPITAL INSTRUMENTS/STAINLESS STEEL INTRUM	INDOOR MEDICAL
HOSPITAL PREMISES/LABORATORIES	INDOOR MEDICAL
VETERINARY HOSPITAL PREMISES/MATERIALS	INDOOR MEDICAL
HEMODIALYSIS MACHINES/HOSPITAL MATERIALS	INDOOR MEDICAL
BEDPANS	INDOOR MEDICAL
FLOOR MATS/FLOORS	INDOOR RESIDENTIAL
INDUSTRIAL PREMISES/EQUIP.	INDOOR NON-FOOD
LOCKER/SHOWER ROOM PREMISES	INDOOR NON-FOOD
STORES	INDOOR FOOD
"	INDOOR NON-FOOD
BEDDING-HUMAN/SHOWER CURTAINS	INDOOR RESIDENTIAL
LAUNDRY/EQUIP.	INDOOR RESIDENTIAL
DIAPERS/DIAPER PAILS	INDOOR RESIDENTIAL
"	INDOOR NON-FOOD
BATHROOM PREMISES/SHOWER STALLS/TOILETS	INDOOR RESIDENTIAL
URINALS	INDOOR RESIDENTIAL
CUSPIDORS	INDOOR MEDICAL
GARBAGE STORAGE PREMISES/CONTAINERS/CANS	INDOOR RESIDENTIAL
ENVIRONMENTAL INANIMATE HARD SURFACES	INDOOR MEDICAL
"	INDOOR RESIDENTIAL
AIR TREATMENT-FOOD PROCESS PLANT	INDOOR FOOD
SURFACES	INDOOR NON-FOOD
"	INDOOR FOOD
"	INDOOR MEDICAL
BATHHOUSE SURFACES/SHOWER SURFACES	INDOOR RESIDENTIAL
HARD NONPOROUS SURFACES/HD POROUS SURFACES	INDOOR NON-FOOD
"	INDOOR FOOD
"	INDOOR MEDICAL
ROOFS (ASPHALT AND WOOD)	RESIDENTIAL OUTDOOR
WOOD SURFACES-SEASONED/UNPAINTED	RESIDENTIAL OUTDOOR
FABRIC SURFACES	INDOOR RESIDENTIAL
HUMAN CLOTHING	INDOOR RESIDENTIAL
LAUNDRY (HOSPITAL)	INDOOR MEDICAL
LAUNDRY (COIN-OPERATED	INDOOR RESIDENTIAL
LAUNDRY (HOUSEHOLD)	INDOOR RESIDENTIAL
FUNITURE (OUTDOOR)	RESIDENTIAL OUTDOOR
STOVE SURFACES	INDOOR RESIDENTIAL

USE GROUP SUMMARY: TERRESTRIAL FOOD CROP, TERRESTRIAL FEED CROP, TERRESTRIAL NON-FOOD CROP, AQUATIC FOOD CROP, AQUATIC NON-FOOD OUTDOOR, AQUATIC NON-FOOD INDUSTRIAL, AQUATIC NON-FOOD RESIDENTIAL, RESIDENTIAL OUTDOOR, INDOOR FOOD, INDOOR NON-FOOD, INDOOR MEDICAL, INDOOR RESIDENTIAL.

APPENDIX B

Generic Data Requirements for Reregistration of Sodium or Calcium Hypochlorite and Data Citations Supporting Reregistration

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix B contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Any other designations will be defined in a footnote to the table.

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Product Identity	ABCDEFGKLMNO	00007588
*61-2a	Begin. Mat. and MFG Process	ABCDEFGKLMNO	00007588, 00007226, 00007269, 00025213
*61-2b	Discussion of Impurities	ABCDEFGKLMNO	00007226, 00007588
62-1	Preliminary Analysis	ABCDEFGKLMNO	00007227, 00007271, 00007588, 05011175
63-2	Color	ABCDEFGKLMNO	00007226
63-3	Physical State	ABCDEFGKLMNO	00007226
63-4	Odor	ABCDEFGKLMNO	00007226
63-7	Density	ABCDEFGKLMNO	00007226
63-12	pH	ABCDEFGKLMNO	00007226
63-13	Stability	ABCDEFGKLMNO	00007226

* These guideline numbers were previously 61-2 and 61-3, respectively.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Ecological Effects:			
71-1a	Acute avian oral - Quail	ABCDEFGKLMNO	00007276, 00007403
71-2a	Acute avian dietary - Quail	ABCDEFGKLMNO	00007275, 00007405
71-2b	Acute avian dietary - Duck	ABCDEK	00007278, 00007404
72-1a	Fish tox - Bluegill	ABCDEFK	00008190, 00007401, 40911802
72-1c	Fish tox - Rainbow trout	ABCDEFGKLMNO	00008191, 00007400, 40911802
72-2a	Invertebrate tox	ABCDEFGKLMNO	00007279, 00007402, 000019313, 40911802
72-3a	Estu/Mari Tox Fish	ABCDEFK	40911802
72-3b	Estu/Mari Tox Mollusk	ABCDEFK	40911802
72-3c	Estu/Mari Tox Shrimp	ABCDEFK	40911802
72-4a	Early Life Stage Fish	ABCDEFK	40911802
72-4b	Life Cycle Invertebrate	ABCDEFK	40911802
72-5	Life Cycle Fish	ABCDEFK	40911802
72-7	Field Testing - Aquatic Org	ABCDEFK	40911802

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology			
81-1	Acute oral tox - rat	ABCDEFGKLMNO	00007540, 00020072, 00007397, 00007285, 00007274, 00007399, 00007374, 00007369
81-2	Acute dermal tox - rabbit	ABCDEFGKLMNO	00007374, 00007369,00007285, 00007277, 00007398, 00020072, 00007540
81-4	Primary eye irritation - rabbit	ABCDEFGKLMNO	00007374, 00007369, 00007274, 00008204, 00008206, 00007221, 00020072, 00007540
81-5	Primary dermal irritation - rabbit	ABCDEFGKLMNO	00007374, 00007369, 00007274, 00008203, 00008205, 00007221, 00020072, 00007540

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Environmental Fate:			
161-1	Hydrolysis	ABCDEFGK	40911802
161-2	Photodegradation - water	ABCDEFGK	05011199
162-3	Anaerobic aquatic metab	ABCDEFG	40911802
162-4	Aerobic aquatic metab	DEFG	40911802, 05021388
164-2	Aquatic field dissipation	DEFG	40911802
165-3	Accumulation-irrig crop	DEF	40911802

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CALCIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Product Identity	ABCDEFGKLMNO	00007498
*61-2a	Begin. Mat. and MFG Process	ABCDEFGKLMNO	00007498, 05014892, 05012141
*61-2b	Discussion of Impurities	ABCDEFGKLMNO	40929401
62-1	Preliminary Analysis	ABCDEFGKLMNO	00007498, 05011175
63-2	Color	ABCDEFGKLMNO	00007498
63-3	Physical State	ABCDEFGKLMNO	00007498, 05009652
63-4	Odor	ABCDEFGKLMNO	00007498
63-7	Density	ABCDEFGKLMNO	40929401
63-12	pH	ABCDEFGKLMNO	40929401

* These guideline numbers were previously 61-2 and 61-3, respectively.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CALCIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Ecological Effects:			
71-1a	Acute avian oral - Quail	ABCDEFGKLMNO	00007496, 40230102
71-2a	Acute avian dietary - Quail	ABCDEFGKLMNO	00007275, 00007405, 40230104
71-2b	Acute avian dietary - Duck	ABCDEK	00007278, 00007404, 40230103
72-1a	Fish tox - Bluegill	ABCDEFK	40911811, 40911802
72-1c	Fish tox - Rainbow trout	ABCDEFGKLMNO	00007495, 40911802
72-2a	Invertebrate tox	ABCDEFGKLMNO	00007495, 40911802
72-3a	Estu/Mari Tox Fish	ABCDEFK	40911802
72-3b	Estu/Mari Tox Mollusk	ABCDEFK	40911802
72-3c	Estu/Mari Tox Shrimp	ABCDEFK	40911802
72-4a	Early Life Stage Fish	ABCDEFK	40911802
72-4b	Life Cycle Invertebrate	ABCDEFK	40911802
72-5	Life Cycle Fish	ABCDEFK	40911802
72-7	Field Testing - Aquatic Org	ABCDEFK	40911802

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CALCIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology			
81-1	Acute oral tox - rat	ABCDEFGKLMNO	00007381, 00007580
81-2	Acute dermal tox - rabbit	ABCDEFGKLMNO	00007381
81-3	Acute Inhalation - rat	ABCDEFGKLMNO	00007560, 00007580
81-4	Primary eye irritation - rabbit	ABCDEFGKLMNO	00007580, 00007381, 00007248, 00007249
81-5	Primary dermal irritation - rabbit	ABCDEFGKLMNO	00007580, 00007381, 00008202, 00007248

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CALCIUM HYPOCHLORITE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Environmental Fate:			
161-1	Hydrolysis	ABCDEFGK	40911802
161-2	Photodegradation - water	ABCDEFGK	05011199
162-3	Anaerobic aquatic metab	ABCDEFG	40911802
162-4	Aerobic aquatic metab	DEFG	40911802, 05021388
164-2	Aquatic field dissipation	DEFG	40911802
165-3	Accumulation-irrig crop	DEF	40911802

APPENDIX C

SODIUM AND CALCIUM HYPOCHLORITE BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX C

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 Reregistration Eligibility Document. 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 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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APPENDIX D

PR NOTICE 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

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The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE**," a currently registered products as well as all applications for ne registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be set based on representative sampling and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient statements must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentration" on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

United States
Environmental Protection
Agency

Office of
Pesticide Programs

October 1991

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Pesticide Reregistration Handbook

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PESTICIDE REREGISTRATION HANDBOOK

HOW TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED)

OFFICE OF PESTICIDE PROGRAMS

ENVIRONMENTAL PROTECTION AGENCY

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PRODUCT REREGISTRATION HANDBOOK

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PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its s and its regulatory history; describes EPA's decision concernir eligibility of the uses of the chemical for reregistration, i explains the scientific and regulatory bases for this decision. EPA's reviews[1] of the data by scientific discipline are available upon request. Appendices to the RED contain: (1) a Data Dall-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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[1] EPA's science reviews and information on the registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

--whether all of the product specific data and labels/labeling are acceptable,

--whether all of the uses on the label/labeling are eligible,

--whether all of the active ingredients in the product are eligible, and

--if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be reregistered. Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as amendments in order to implement label changes required by the RED.

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1 summarizes how and when to respond to the RED. A step-by-step explanation follows.

Step 1. Are Expedited Label Changes Required? In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED. If expedited label changes are not required, go to Step 2.

a. Application for Registration (EPA Form 8570-1). Complete

and sign the form. In Section II, insert the phrase "**Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical).**" Applications for expedited label changes will be processed as applications for amended registration. **Use only an original application form with a red identifier number in the upper right-hand corner.**

b. **Five (5) copies of revised draft label and labeling.** Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? **If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.**

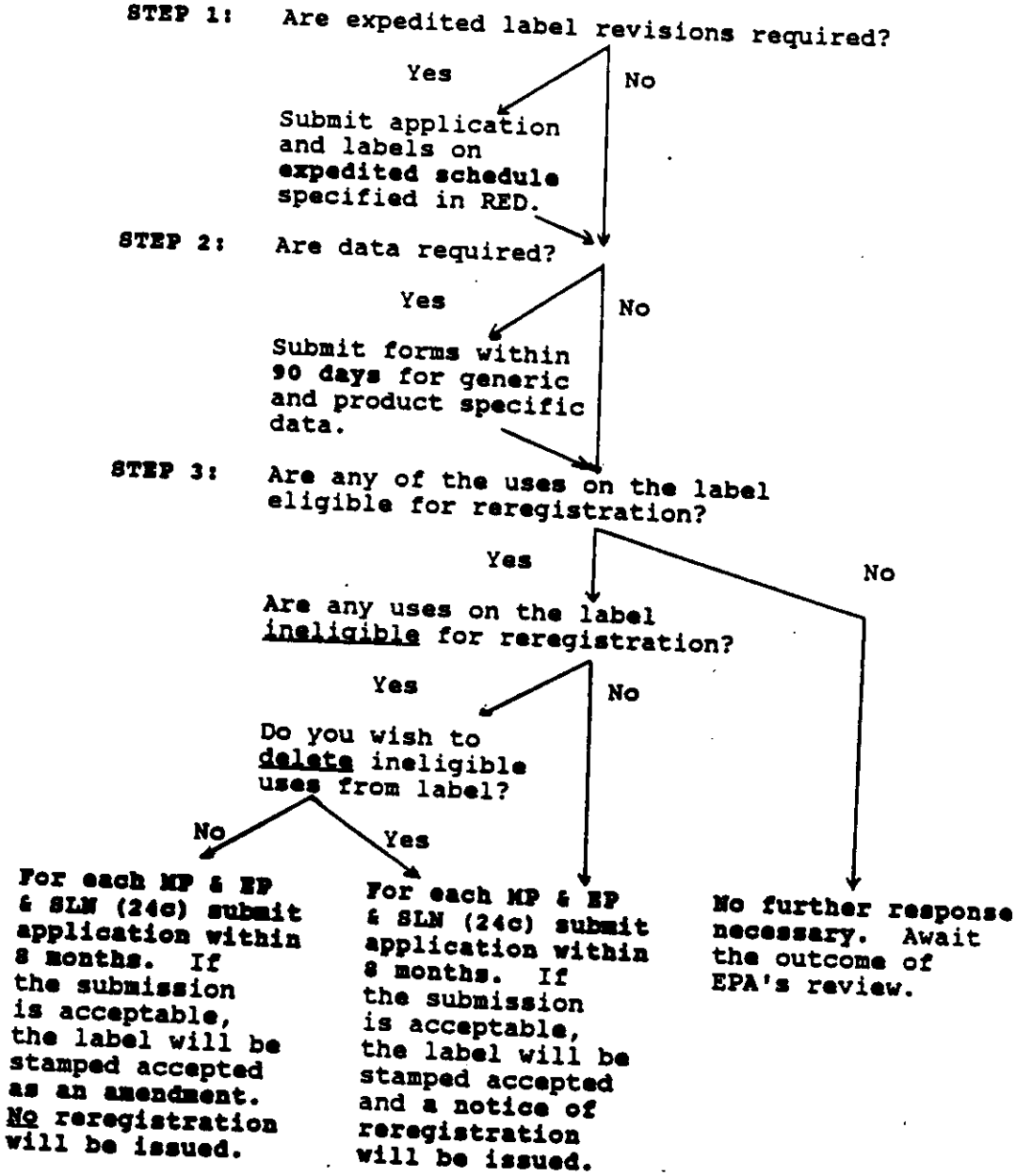
Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. **If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) an special local needs registrations (SLNs), must submit the ite below for each product within 8 months of the date of issuance the RED:**

a. **Application for Reregistration (use EPA Form 8570-1).** Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase "**Application for Reregistration.**" **Use only an original application form with a red identifier number in the upper right-hand corner.**

b. **Five (5) copies of revised draft label and labeling.** Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are **ineligible uses** on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).



c. **Product Specific Data.** You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.

d. Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 85). Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation. If CSFs are not provided for the alternate formulas, they will not be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. **Certification With Respect to Citation of Data (EPA Form 8570-31).** This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

B. When No Response is Needed

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.

C. Where to Respond

By U.S. Mail:

Document Processing Desk (**insert distribution code**)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk (**insert distribution code**)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing **generic data**. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing **product specific data or labeling**. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.

Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Dall-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

B. Product Specific Data

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

1. Product Chemistry

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

a. Data

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together a being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

b. Inert Ingredients

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, a product containing a List 1 inert ingredient will <u>not</u> be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient. However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert <u>may</u> be reregistered <u>if</u> it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

2. <u>Acute Toxicity</u>

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each baatch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

3. Product Performance

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing Proposed protocols should be submitted to EPA for review before tests are initiated.

a. Efficacy Data Submission Waiver Policy

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;

2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;

3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;

4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

C. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier. Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

C. Sample Label Formats--General Use & Restricted Use

D. Label Regulations (40 CFR 156.10)

EPA Confidential Statement of Formula

☐ Alternate Formulation

Page of

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr./Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 2-85) Previous editions are obsolete

Original and second copy to EPA
Third copy to Applicant

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product-specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

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. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is normally 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. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

Item 7. WARNINGS AND 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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(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. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. 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.

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). If your product has been classified for restricted use, then these requirements apply:

1. **All uses restricted.** The following statements must be placed in a black box at the top of the front panel of the label and labeling:

   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 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.

   b. The reason for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.

   c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. 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." The RED will specify what statement must be used.

2. **Some but not all uses restricted.** If the RED 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. 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 restricted entry interval (REI) 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. 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 P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

Item 10C. 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. [40 CFR 156.10(i)(2)]

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. Collateral labeling must be made part of the response to the RED and submitted for review.

LABEL FORMAT FOR UNCLASSIFIED PRODUCTS

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS

CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT NAME

ACTIVE INGREDIENT: _____ %
INERT INGREDIENTS: _____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

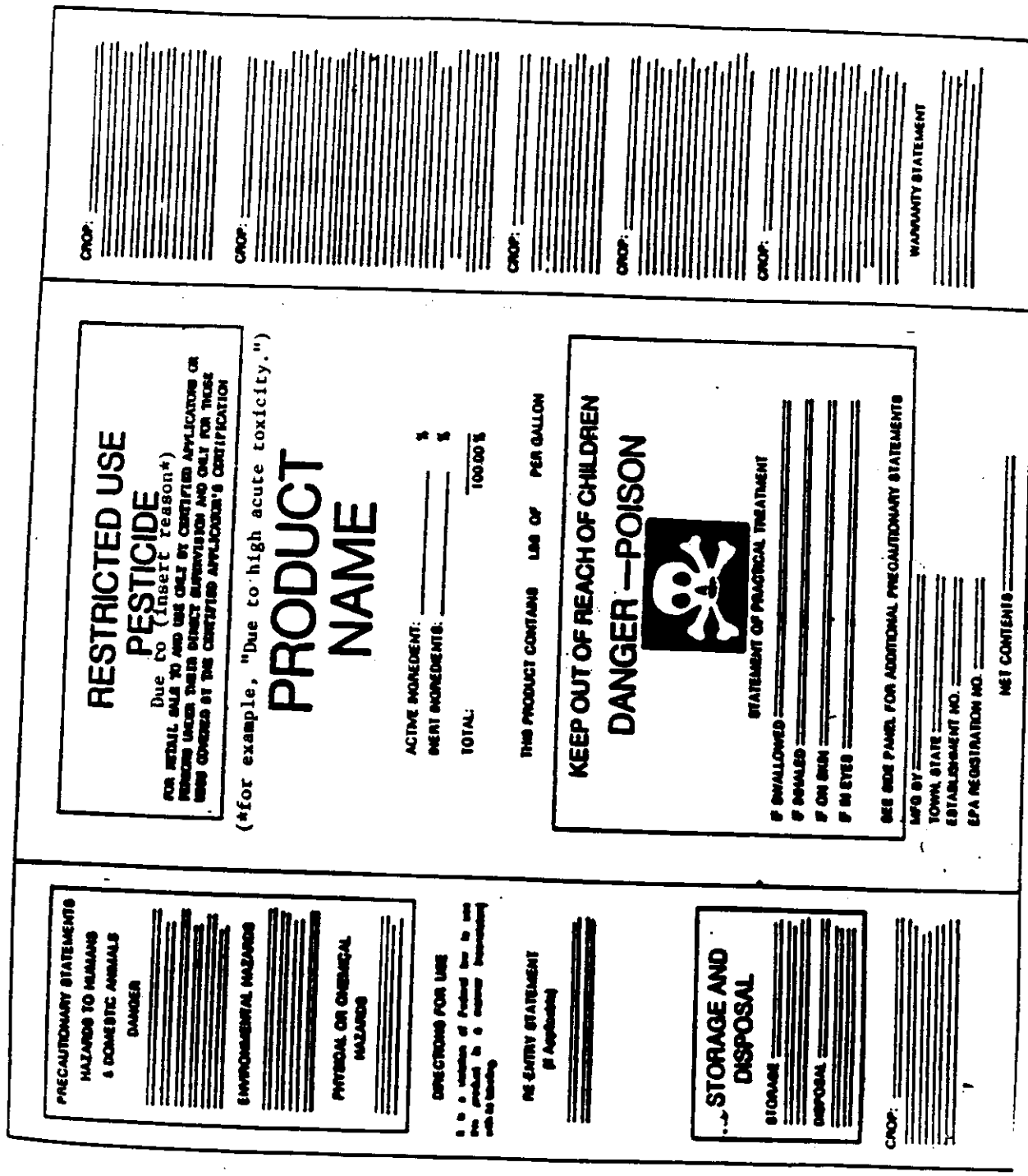
STORAGE AND DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT

LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED USE



submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, E'A will r quire that persons on the list rene their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136-136y.

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide product shall bear a label containing the information specified by the Act and the regu-

lations in this Part. The contents of a label must show clearly and prominently the following:

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

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

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

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

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

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

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

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

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

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

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

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

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

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

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

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

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

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

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

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

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

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

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

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

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

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

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

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

tent of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

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

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

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	8
Above 5 to 10	10	6
Above 10 to 15	12	9
Above 15 to 30	14	10
Over 30	18	12

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

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

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

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

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

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

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

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

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

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

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 34871, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States
Environmental Protection Agency
(H-7508W)
Washington, DC 20460

Official Business
Penalty for Private Use
$300

APPENDIX E

DATA CALL-IN

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DATA CALL-IN NOTICE

CERTIFIED MAIL

FEB 28 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment C, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product-specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment F).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

Printed on Recycled Paper

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting

your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment B and Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment A.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice. There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose this option, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agree to Share in Cost to Develop Data --Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been

unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, <u>all of the following three criteria must be clearly met</u>:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " '[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment A. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable

toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency will grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol if such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study if required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer either to:

a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

b. Fulfill the commitment to develop and submit the data as required by this Notice; or

c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for

issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols (if applicable), including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C <u>EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS</u>

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with

all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment B and Attachment C) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment A. If the voluntary cancellation option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

ATTACHMENT A

DATA CALL-IN CHEMICAL STATUS SHEET

ATTACHMENT A

SODIUM AND CALCIUM HYPOCHLORITE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing sodium and calcium hypochlorite.

This attachment, the Data Call-In Chemical Status Sheet, contains the reregistration regulatory history of sodium and calcium hypochlorite, an overview of data required by this notice, and point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, (3) Attachment C, the Requirement Status and Registrant's Response Form for product specific data, (4) Attachment D, EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration, (5) Attachment E, EPA Acceptance Criteria, (6) Attachment F, List of all Registrant(s) sent this Data Call-In Notice, and (7) Attachment G, the Cost Share and Data Compensation Forms for product specific data, and Product Specific Data Report Form for use in replying to this Sodium and Calcium Hypochlorite Data Call-In. Instructions and guidance accompany each form.

REREGISTRATION HISTORY

The Agency issued a Registration Standard entitled "Guidance for the Registration of Pesticide Products Containing As the Active Ingredient Sodium and Calcium Hypochlorite Salts" (NTIS PB87-103222) in February 1986. The registration standard summarized the available data supporting the registration of sodium and calcium hypochlorite and determined that the data were substantially complete. No additional data were required for the generic data base in the 1986 standard. The requirements listed in the standard were cited only for those applicants who wanted to develop their own supporting data rather than rely upon and offer to pay compensation for the data cited in the standard.

Recently, the Agency conducted a thorough review of the scientific data base and all relevant information supporting the reregistration of sodium and calcium hypochlorite and has reevaluated its position on data needed to support the continued registration of sodium and calcium hypochlorite.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for sodium and calcium hypochlorite are listed in the Requirements Status and Registrant's Response, Attachment C.

The Agency has concluded that additional data on sodium and calcium hypochlorite are needed in the following areas: product specific data. The required additional data are listed in Attachment C.

Depending on the results of the studies required in this Notice, additional testing may be required.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Ruth Douglas at (703) 305-7964.

All responses to this Notice should be submitted to:

Document Processing Desk (RED/RD/PM 32)
Office of Pesticide Programs (H7505C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

RE: Sodium and Calcium Hypochlorite

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MP) or 7b (EP) on this form, provide the EPA registration numbers of your source(s) and complete and submit the "Generic Data Exemption" form; you would not complete the "Requirements Status and Registrant's Response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with Option 7 (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

<u>NOTE</u>: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
	0029 Na & Ca Hypochlorite	PRODUCT SPECIFIC FEB 28 1992

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Product Specific Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of product specific data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the unique identifier number assigned by EPA in Item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Document unless EPA determines that a longer time period is necessary.

Item 9. Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement and a completed "Certification With Respect To Data Compensation Requirements" form. I understand that this option is available only for acute toxicity or certain efficacy

data and only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (Upgrading a Study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing

another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address

2. Case # and Name
0029 Na & Ca Hypochlorite

EPA Reg. No.

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 49927-RD-1676
FEB 28 1992

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
61-2(a)	Descrip of starting materials,(1,2) production & formulation proc					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-5	Melting point (6)					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-6	Boiling point (7)					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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PRODUCT SPECIFIC
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FEB 28 1992

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-11	Octanol/water partition (8) coefficient					ABCDEFGHIJKLMNO	MP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/TGAI	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal (1,2) toxicity-rabbit/rat					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address

2. Case # and Name
0029 Na & Ca Hypochlorite

EPA Reg. No.

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 49927-RD-1676
FEB 28 1992

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0029 Na & Ca Hypochlorite

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit pr cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
6 Required if technical chemical is solid at room temperature.
7 Required if technical chemical is liquid at room temperature.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0029 Na & Ca Hypochlorite

Footnotes (cont.):

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING
ACUTE TOXICOLOGY DATA REQUIREMENTS
FOR REREGISTRATION

EPA'S BATCHING OF CALCIUM HYPOCHLORITE AND SODIUM HYPOCHLORITE END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient calcium hypochlorite and sodium hypochlorite, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above. Frequently acute toxicity data on individual end-use products have been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Single active ingredient calcium hypochlorite or sodium hypochlorite products that conform to product composition and specifications prescribed in the Registration Standard of February 1986, titled Guidance for Reregistration of Pesticide Products Containing Calcium and Sodium Hypochlorite Salts (Part I, Section E) have not been included in the batch tables that follow. Due to the very narrow product compositions described in the Registration Standard, all products meeting one of those descriptions would be considered a batch. For example, there would ordinarily have been a batch for products containing only 12.5% sodium hypochlorite and water, another for products containing only 65% calcium hypochlorite and water, etc. In that there were literally hundreds of products that met the criteria established in the Registration Standard, these products have not been listed in the batch tables. The batches in tables I and II below represent those products which did not meet the specifications of the 1986 Registration Standard

Table I shows 5 batches including 28 products containing the active ingredient calcium hypochlorite. Note that another 14 products containing the active ingredient calcium hypochlorite were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of the products which were not batched are responsible for meeting the acute toxicity data requirements for each product.

Table I.

Batch	EPA Reg. No.	% Calcium Hypochlorite	Formulation Type
1.	1258-919	2.5	liquid
	10663-45	5.0	liquid
	10663-18	5.0	liquid
	10876-2	2.5	liquid
2.	1258-915	35.0	granular
	1258-971	35.0	tablets
3.	1258-4	50.0	granular
	1258-1058	55.0	tablets
	1258-1063	50.0	granular
	1258-1067	50.0	tablets
	1258-1068	55.0	granular
	1677-145	50.0	granular
	4829-9	50.0	granular
	4829-10	50.0	tablets
	4829-90	50.0	granular
	4829-110	50.0	granular

Batch	EPA Reg. No.	% Calcium Hypochlorite	Formulation Type
4.	1258-1111	55.0	tablet
	1258-1112	50.0	tablet
	1258-1114	54.0	granular
	1258-1115	55.0	granular
	1258-1116	50.0	granular
	1258-1118	55.0	granular
	1258-1119	54.0	granular
	1258-1120	50.0	granular
5.	1258-978	62.0	granular
	1258-979	62.0	tablets
	1258-1121	60.0	granular
	1258-1122	60.0	granular

Table II shows 3 batches including 28 products containing the active ingredient sodium hypochlorite. Note that another 49 products containing the active ingredient sodium hypochlorite were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of the products which were not batched are responsible for meeting the acute toxicity data requirements for each product.

Table II.

Batch	EPA Reg. No.	% Sodium Hypochlorite	Formulation Type
1.	148-1287	5.25	liquid
	467-1	5.25	liquid
	49614-1	6.0	liquid
	57125-4	6.40	liquid
2.	148-628	10.5	liquid
	148-1288	12.5	liquid
	193-16	12.5	liquid
	2686-20001	12.5	liquid
	7546-3	6.4	liquid
	7547-30	12.5	liquid
	18723-1	11.6	liquid

Batch	EPA Reg. No.	% Sodium Hypochlorite	Formulation Type
3.	264-512	3.25	wettable powder
	875-41	3.25	powder
	875-111	3.25	powder
	1043-98	3.25	powder
	1190-14	3.25	powder
	1677-19	3.25	powder
	1677-139	3.25	powder
	4462-15	3.25	wettable powder
	5736-37	3.22	wettable powder
	5991-2	3.25	powder
	6484-1	3.25	wettable powder
	8616-12	3.25	granular
	8898-14	3.75	powder
	10508-3	3.25	powder
	10634-2	3.25	powder
	11741-12	3.25	powder
	35495-7	3.25	powder

The following tables show products that were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table III.

EPA Reg. No.	% calcium hypochlorite	Formulation type
475-224	19.5	granular
1020-5	9.0	powder
1258-911	60.0	granular
1258-1110	54.0	tablet
1258-1149	59.1	tablet
1258-1150	59.1	tablet
1730-56	60.0	liquid
4829-4	70.0	granular
5389-13	0.65	liquid
5680-5	15.0	liquid

10876-1	38.0	liquid
48482-1	69.30	tablets
48520-7	63.6	granular
49592-1	63.4	

Table IV.

EPA Reg. No.	% sodium hypochlorite	Formulation type
402-94	0.325	powder
475-218	2.4	liquid
491-206	0.4	powder
602-168	3.25	crystals
777-58	0.7	liquid
1258-726	3.25	liquid
1315-2	5.25	liquid
1317-86	8.5	liquid
1453-24	5.25	liquid
1677-51	6.40	liquid
1706-171	8.34	liquid
1816-5	3.25	liquid
2686-1	3.25	wettable powder
2792-62	12.5	liquid
3276-25	6.6	liquid
3522-21	6.0	liquid
3573-46	0.5	liquid
3640-64	6.4	liquid
4238-25	8.0	liquid
4313-75	5.25	liquid
4524-21	3.25	wettable powder
4587-2	12.5	liquid
5736-2	1.94	granular
5736-9	1.0	wettable powder
5768-9	3.25	wettable powder
5813-20	5.25	liquid
5813-21	2.0	liquid
5813-23	0.45	liquid
5813-24	1.65	liquid

EPA Reg. No.	% sodium hypochlorite	Formulation type
5813-25	0.7	liquid
5870-13	3.25	wettable powder
5870-17	1.95	granular
7350-2	3.25	wettable powder
7726-24	6.0	liquid
9367-37	10.0	liquid
10183-6	3.09	liquid
10380-1	5.25	liquid
17004-3	5.25	liquid
17705-2	5.25	liquid
20851-4	10.0	liquid
34093-4	10.0	liquid
38623-20002	10.0	liquid
46183-1	6.4	liquid
46506-1	0.6	liquid
47230-1	2.5	liquid
57125-1	5.25	liquid
57787-4	10.0	liquid
59893-3	4.5	liquid
62207-1	5.25	liquid

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

61 Product Identity and Composition 4
62 Analysis and Certification of Product Ingredients 6
63 Physical and Chemical Characteristics 8

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Name of technical material tested (include product name and trade name, if appropriate)
2. ___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3. ___ Name and upper certified limit for each impurity or each group of impurities present at ≥ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%
4. ___ Purpose of each active ingredient and each intentionally-added inert
5. ___ Chemical name from Chemical Abstracts Index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6. ___ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
7. ___ Description of each beginning material in the manufacturing process
   - ___ EPA Registration Number if registered; for other beginning materials, the following:
   - ___ Name and address of manufacturer or supplier
   - ___ Brand name, trade name or commercial designation
   - ___ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity
8. ___ Description of manufacturing process
   - ___ Statement of whether batch or continuous process
   - ___ Relative amounts of beginning materials and order in which they are added
   - ___ Description of equipment
   - ___ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained
   - ___ Statement of whether process involves intended chemical reactions
   - ___ Flow chart with chemical equations for each intended chemical reaction
   - ___ Duration of each step of process
   - ___ Description of purification procedures
   - ___ Description of measures taken to assure quality of final product
9. ___ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at ≥ 0.1% or was found at ≥ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3)

Criteria marked with a * are supplemental and may not be required for every study.

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 1, 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement of Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration, and certified limits.
3. Name and upper limit for all impurities present at ≥ 0.1% and those toxicologically significant impurities present at <0.1%.
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental or internal code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at ≥ 0.1%
2. ___ Degree of accountability or closure ≥ ca 98%
3. ___ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans) [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]
4. ___ Complete and detailed description of each step in analytical method used to analyze above samples
5. ___ Statement of precision and accuracy of analytical method used to analyze above samples
6. ___ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient
7. ___ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined
8. ___ Upper certified limit proposed for each impurity present at ≥ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined
9. ___ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described
10. ___ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy

Criteria marked with a * are supplemental and may not be required for every study.

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Number of representative samples analyzed for all active ingredients and all impurities present at ≥ 0.1%.

2. Degree of accountability or closure in analyses in item #1.

3. Chemical names of toxic impurities which were analyzed for levels <0.1%.

4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.

5. Statement of precision and accuracy of method(s) in item #4.

6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.

7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.

8. Proposed upper certified limit for each impurity present at >=0.1% and certain toxicologically significant impurities at <0.1% with brief explanation of how limits were determined.

9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).

10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

___ Verbal description of coloration (or lack of it)
___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

___ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
___ Based on visual inspection at about 20-25°C

63-4 Odor

___ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
___ Observed at room temperature

63-5 Melting Point

___ Reported in °C
___ Any observed decomposition reported

63-6 Boiling Point

___ Reported in °C
___ Pressure under which B.P. measured reported
___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

___ Measured at about 20-25°C
___ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20°C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

___ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
___ Measured at about 20-25°C
___ Reported in g/100ml (other units like ppm acceptable if sparingly soluble)

Criteria marked with a * are supplemental and may not be required for every study.

63-9 Vapor Pressure

- ___ Measured at ≈25°C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25°C)
- ___ Experimental procedure described
- ___ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

- ___ Experimental method described
- ___ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

- ___ Measured at about 20-25°C
- ___ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
- ___ Data supporting reported value provided

63-12 pH

- ___ Measured at about 20-25°C
- ___ Measured following dilution or dispersion in distilled water

63-13 Stability

- ___ Sensitivity to metal ions and metal determined
- ___ Stability at normal and elevated temperatures
- ___ Sensitivity to sunlight determined

Criteria marked with a * are supplemental and may not be required for every study.

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Description of color.
2. Description of physical state.
3. Description of odor.
4. Indication of melting point (in °C).
5. Indication of boiling point (in °C).
6. Indication of density, bulk density, and specific gravity.
7. Indication of solubility.
8. Indication of vapor pressure.
9. Indication of dissociation constant.
10. Indication of octanol/water partition coefficient.
11. Indication of pH.
12. Description of stability.

SUBDIVISION F

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81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2.* ____ At least 5 young adult rats/sex/group
3. ____ Dosing, single oral may be administered over 24 hrs.
4.* ____ Vehicle control if other than water.
5. ____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6. ____ Individual observations at least once a day.
7. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8. ____ Individual daily observations.
9.* ____ Individual body weights.
10.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing.
7. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
8. See items 6 and 7
9. Summarization of body weights
10. Summarization of gross necropsy
11. Significance of changes from the Acceptance Criteria

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2.* ____ At least 5 animals/sex/group
3.* ____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4. ____ Dosing, single dermal.
5. ____ Dosing duration at least 24 hours.
6.* ____ Vehicle control, only if toxicity of vehicle is unknown.
7. ____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8. ____ Application site clipped or shaved at least 24 hours before dosing
9. ____ Application site at least 10% of body surface area.
10. ____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. The number of animals/sex/dose
3. Weight range of animals
4. Verification of single, dermal exposure
5. Duration of dermal exposure
6. Statement of vehicle control
7. Doses tested and results
8. Preparation of application site
9. Area of application site (percent body surface)
10. Occlusion of test material on application site
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 um or less).
3.* ____ At least 5 young adult rats/sex/group
4.* ____ Dosing, at least 4 hours by inhalation.
5.* ____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6. ____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7. ____ Monitor rate of air flow
8. ____ Monitor actual concentrations of test material in breathing zone.
9. ____ Monitor aerodynamic particle size for aerosols.
10. ____ Doses tested, sufficient to determine a toxicity catagory or a limit dose (5 mg/L actual concentration of respirable substance).
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. Statement of the inhalability of test substance
3. The number of animals/sex/dose
4. Duration of inhalation exposure
5. Number of chamber air changes/hour and the percent oxygen content of chamber air
6. Ranges for chamber air temperature and relative humidity
7. Air flow rate
8. Analytical concentrations of test material in breathing zone
9. Results of aerosol particle-size determination
10. Doses tested (or limit dose of 5mg/L or highest attainable)
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.* ____ 6 adult rabbits
4. ____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.* ____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6. ____ Solid or granular test material ground to a fine dust.
7. ____ Eyes not washed for at least 24 hours.
8. ____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.* ____ Individual observations for the entire day of dosing.
10.* ____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State of material is corrosive, cause severe dermal irritation or has a pH of <2 or >11.5
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual observations for entire day of dosing
10. Individual observations for entire day of dosing and individual daily observations afterwards, until eyes are normal or for 21 days
11. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.* ____ 6 adult animals.
4. ____ Dosing, single dermal.
5. ____ Dosing duration 4 hours.
6. ____ Application site shaved or clipped at least 24 hour prior to dosing.
7. ____ Application site approximately 6 cm^2.
8. ____ Application site covered with a gauze patch held in place with nonirritating tape
9. ____ Material removed, washed with water, without trauma to application site
10. ____ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.* ____ Individual observations for the entire day of dosing.
12.* ____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD-50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for entire day of dosing.
12. Individual observations for entire day of dosing and individual daily observations thereafter
13. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3. ____ One of the following methods is utilized;
   - ____ Freund's complete adjuvant test
   - ____ Guinea pig maximization test
   - ____ Split adjuvant technique
   - ____ Buehler test
   - ____ Open epicutaneous test
   - ____ Mauer optimization test
   - ____ Footpad technique in guinea pig
   - ____ Other test accepted by OECD (specify)_____
4. ____ Complete description of test
5.* ____ Reference for test.
6. ____ Test followed essentially as described in reference document.
7.* ____ Positive control included.

Criteria marked with a * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive or has pH <2 or >11.5).
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

81-7 Acute Neurotoxicity in the Hen

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Study performed on an organophosphate cholinesterase inhibiting compound.
2. ____ Technical form of the active ingredient tested.
3.* ____ Positive control utilized.
4. ____ Species utilized, domestic laying hen 8-14 months of age.
5. ____ Dosing oral by gavage or capsule (dermal or inhalation may be used).
6. ____ An acute oral LD_{50} is determined.
7. ____ Dose tested equal to an acute oral LD_{50} or a limit test of 5000 mg/kg.
8.* ____ Dosed animals may be protected with atropine and/or 2-PAM.
9. ____ Sufficient test animals so that at least 6 survive.
10. ____ Negative (vehicle) control group of at least 6 hens
11.* ____ Positive control of at least 4 hens. (if used)
12. ____ Test dose repeated if no signs of delayed neurotoxicity observed by 21 days after dosing.
13. ____ Observation period 21 days after each dose.
14. ____ Individual daily observations.
15. ____ Individual body weights.
16.* ____ Individual necropsy not required.
17. ____ Histopathology performed on all animals. Tissue to be fixed *in situ* preferably using whole animal perfusion techniques. At least three sections of each of the following tissues:
    - ____brain, including medulla oblongata
    - ____spinal cord; upper cervical, mid-thoracic and lumbro-sacral regions
    - ____tibial nerve; proximal regions and branches
    - ____sciatic nerve

Criteria marked with a * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF ALL REGISTRANT(S) SENT THIS DATA CALL-IN NOTICE

Companies for Case 0029 NA & CA Hypochlorite
Printed: 02/10/92 16:28

CO NR	CO NAME		
000110	MADISON CHEMICAL COMPANY, INC		
BOX 125		MADISON IN	47250
000148	HARCROS CHEMICALS INC.		
BOX 2383		KANSAS CITY KS	66110
000150	ANDERSON CHEMICAL CO.		
BOX 1041		LITCHFIELD MN	55355
000168	GREAT WESTERN CHEMICAL COMPANY		
808 S.W. 15TH AVE.		PORTLAND OR	97205
000193	WONDER CHEMICAL CORP		
249 CANAL RD PENN WARNER IND PARK		FAIRLESS HILLS PA	19030
000228	RIVERDALE CHEMICAL CO		
425 WEST 194TH ST.		GLENWOOD IL	60425
000266	HILL BROTHERS CHEMICAL CO.		
1675 N. MAIN STREET		ORANGE CA	92667
000278	MIAMI PRODUCTS & CHEMICAL COMPANY		
P.O. BOX 486		DAYTON OH	45401
000402	HILL MANUFACTURING CO., INC.		
1500 JONESBORO RD SE		ATLANTA GA	30315
000467	BARTON CHEMICAL CORPORATION		
5331 WEST 66TH STREET		CHICAGO IL	60638
000475	BOYLE-MIDWAY		
1655 VALLEY RD		WAYNE NJ	07474
000491	SELIG CHEMICAL INDUSTRIES THE		
840 SELIG DR SW		ATLANTA GA	30378
000550	VAN WATERS & ROGERS, INC	SUBSIDIARY OF UNIVAR	
801 SECOND AVE, SUITE 1600		SEATTLE WA	98104
000602	PURINA MILLS, INC.		
BOX 66812		ST LOUIS MO	63166
000662	BASF CORP		
BOX 13528		RESEARCH TRIANGLE PARK NC	27709
000748	PPG INDUSTRIES, INC	PRODUCT SAFETY	
ONE PPG PLACE		PITTSBURGH PA	15272
000777	L & F PRODUCTS		
225 SUMMIT AVENUE		MONTVALE NJ	07645
000813	DPC INDUSTRIES, INC.		
300 JACKSON HILL		HOUSTON TX	77007

CO NR	CO NAME		
000833	ALEX C. FERGUSSON, INC SPRING MILL DR	FRAZER PA	19355
000875	DIVERSEY CORP 1532 BIDDLE AVE.	WYANDOTTE MI	48192
000935	OCCIDENTAL CHEMICAL CORPORATION DEVELOPMENT CENTER, V-81 BOX 344	NIAGARA FALLS NY	14302
001020	OAKITE PRODUCTS INC 50 VALLEY RD	BERKELEY HEIGHTS NJ	07922
001043	CALGON VESTAL LABORATORIES BOX 147	DIVISION OF CALGON CORPORATION ST LOUIS MO	63166
001072	BABSON BROTHERS COMPANY, CHEMICAL DIVISION 1354 ENTERPRISE DRIVE	ROMEOVILLE IL	60441
001190	J.F. DALEY INTERNATIONAL, LTD. 1200 SWITZER AVE	PECKS PRODUCTS DIVISION ST LOUIS MO	63147
001258	OLIN CORPORATION BOX 586	CHESHIRE CT	06410
001270	ZEP MANUFACTURING COMPANY BOX 2015	ATLANTA GA	30301
001317	AN-FO MANUFACTURING COMPANY 3129 ELMWOOD AVE. BOX 7311	OAKLAND CA	94601
001421	DETTELBACH CHEMICAL COMPANY 4309 SOUTH MORGAN STREET	DIVISION OF MYSAN CORPORATION CHICAGO IL	60609
001448	BUCKMAN LABS INC 1256 MCLEAN BLVD	MEMPHIS TN	38108
001453	PRESCOTT J L COMPANY 16750 SOUTH VICENNES ROAD	SOUTH HOLLAND IL	60473
001553	MOMAR INCORPORATED 1830 ELLSWORTH INDUSTRIAL DRIVE	ATLANTA GA	30318
001672	JAMES AUSTIN COMPANY BOX 827	MARS PA	16046
001677	ECOLAB INC. 370 WABASHA ST. ECOLAB CENTER	ST PAUL MN	55102
001691	TRUETECH, INC 680 ELTON AVENUE	RIVERHEAD NY	11901
001706	NALCO CHEMICAL CO. ONE NALCO CENTER	NAPERVILLE, IL	60563
001717	DOOWER & SMITH CHEMICAL CO. 374 MALBERRY STREET	NEWARK NJ	07102

CO NR	CO NAME		
001729	HYDROTECH CHEMICAL CORP		
BOX 67		DECATUR GA	30031
001730	AMERICAN CYANAMID COMPANY		
697 ROUTE 46		CLIFTON NJ	07015
001744	JONES CHEMICALS, INC.		
80 MUNSON STREET		LEROY NY	14482
001757	DREW INDUSTRIAL DIVISION	ASHLAND CHEMICAL, INC.	
BOX 2219		COLUMBUS OH	43216
001791	SAVOLITE INC		
10848 E MARGINAL WAY SO.		SEATTLE WA	98168
001803	CONTINENTAL CHEMICAL COMPANY INC		
4660 SPRING GROVE AVENUE		CINCINNATI OH	45232
001816	TURCO PRODUCTS, INC.	SUBSIDIARY OF PENNWALT CORPORATION	
7300 BOLSA AVENUE		WESTMINSTER CA	92684
001964	NEW SOUTH MANUFACTURING COMPANY	DIVISION OF HYSAN CORPORATION	
4309 SOUTH MORGAN STREET		CHICAGO IL	60609
002136	HOFFMAN, J.L. CO., INC.		
BOX 8656		ALLENTOWN PA	18105
002230	WARSAW CHEMICAL COMPANY INC		
ARGONNE RD BOX 858		WARSAW IN	46580
002439	APPERSON CHEMICAL		
2903 STRICKLAND STREET		JACKSONVILLE FL	32205
002528	ERBRICH PRODUCTS COMPANY-FOOD & CHEMICAL PRODUCTS		
P.O. BOX 55107		INDIANAPOLIS IN	46205
002686	HYDRITE CHEMICAL CO.		
2655 NORTH MAYFAIR ROAD		MILWAUKEE WI	53226
002792	ATOCHIM NORTH AMERICA		
BOX 120		MONROVIA CA	91016
003276	A & L LABORATORIES INC		
1001 GLENWOOD AVENUE		MINNEAPOLIS MN	55405
003404	NORTHRUP KING CO.		
7500 OLSON MEMORIAL HWY		MINNEAPOLIS MN	55427
003432	N. JONAS & CO., INC.		
4520 ADAMS CIRCLE BOX 425		BENSALEM PA	19020
003522	LUSEAUX LABS INC		
16816 SO GRAMERCY PL.		GARDENIA CA	90247
003525	UTIKEM PRODUCTS	DIVISION OF QUALCO, INC.	
225 PASSAIC STREET BOX 357		PASSAIC NJ	07055

CO NR	CO NAME		
003573	THE PROCTER & GAMBLE CO.		
6060 CENTER HILL ROAD		CINCINNATI OH	45224
003635	OXFORD CHEMICALS		
PO BOX 80202		ATLANTA GA	30366
003640	STEARNS PACKAGING CORP.		
BOX 3216		MADISON WI	53704
003876	BETZ LABORATORIES, INC.		
4636 SOMERTON ROAD		TREVOSE PA	19053
004075	JERRY LEE CHEMICAL CO.		
BOX 17186		PENSACOLA FL	32522
004166	DOMINION CHEMICAL COMPANY		
BOX 1069		PETERSBURG VA	23804
004238	DIAMOND CHEM COMPANY		
BOX 916		LYNDHURST NJ	07071
004313	CARROLL COMPANY		
2900 W. KINGSLEY RD.		GARLAND TX	75041
004462	USC A DIVISION OF HYDRITE CHEMICAL CO.		
2655 NORTH MAYFAIR RD.		MILWAUKEE WI	53226
004524	H.B. FULLER COMPANY		
3900 JACKSON ST., N.E.		MINNEAPOLIS MN	55421
004587	MILPORT CHEMICAL COMPANY		
2829 SOUTH 5TH COURT		MILWAUKEE WI	53207
004635	MASTER CHEMICAL COMPANY		
642 N TILLAMOOK ST		PORTLAND OR	97227
004829	COSTAL INDUSTRIES		
225 PASSAIC STREET		PASSAIC NJ	07055
004959	WEST AGRO, INC.		
11100 NORTH CONGRESS AVENUE		KANSAS CITY MO	64153
005009	PETROLITE CORPORATION		
369 MARSHALL AVENUE		ST LOUIS MO	63119
005185	BIO-LABS INC		
BOX 1489		DECATUR GA	30031
005389	KAY CHEMICAL COMPANY		
BOX 18407		GREENSBORO NC	27419
005568	HUBBARD-HALL INC		
563 S LEONARD ST		WATERBURY CT	06708
005680	SNEE CHEMICAL COMPANY		
1383 TCHOUPITOULAS ST.		NEW ORLEANS LA	70130

CO NR	CO NAME			
005736	JOE D. SLONE	AGENT FOR: DUBOIS CHEMICALS INC		
3630 E KEMPER RD			SHARONVILLE OH	45241
005768	SPURRIER CHEMICAL COMPANIES INC.			
BOX 2812			WICHITA KS	67201
005770	THORO PRODS COMPANY			
BOX 504			ARVADA CO.	80002
005813	CLOROX CO			
BOX 493			PLEASANTON CA	94566
005870	TEXO CORP			
2801 HIGHLAND AVE			CINCINNATI OH	45212
005991	THEOCHEM LABORATORIES INC	AGENT FOR: TIME PRODUCTS INC		
7373 ROWLETT PARK DR			TAMPA FL	33610
006243	AUTO-CHOR SYSTEM			
746 POPLAR AVE			MEMPHIS TN	38105
006284	RICHEY INDUSTRIES, INC.			
BOX 928			MEDINA OH	44258
006671	GEORGE MANN & CO., INC.			
BOX 9066			PROVIDENCE RI	02940
006785	P B & S CHEMICAL COMPANY, INC.			
RT. 2, HIGHWAY 136 WEST BOX 20			HENDERSON KY	42420
006830	OCTAGON PROCESS INC			
596 RIVER RD			EDGEWATER NJ	07020
006931	MERIT CHEMICAL INC			
BOX 513			SHARON WI	53585
006975	CLEARWATER DISTRIBUTORS INC			
2 ROOSEVELT AVENUE			WOODRIDGE NY	12789
007116	U.N.X. INC.			
BOX 7206			GREENVILLE NC	27835
007124	ALDEN LEEDS INC			
55 JACOBUS AVE.			SOUTH KEARNY NJ	07032
007151	ALEXANDER CHEMICAL CORPORATION			
BOX 248			LEMONT IL	60439
007267	SAVOL BLEACH COMPANY			
433 PARK AVE.			EAST HARTFORD CT	06018
007299	THE BRENCO CORPORATION			
1470 S. VANDEVENTER			ST LOUIS MO	63110
007350	CHASKA CHEMICAL COMPANY			
12502 XENWOOD AVE. SOUTH			SAVAGE MN	55378

CO NR	CO NAME		
007364	GREAT LAKES BIOCHEMICAL CO., INC.		
6120 WEST DOUGLAS AVENUE		MILWAUKEE WI	53218
007368	GROW GROUP, INC.		
2501 MALT AVENUE		CITY OF COMMERCE CA	90040
007546	U S CHEMICAL	A DIVISION OF HYDRITE CHEMICAL CO.	
300 N PATRICK BLVD (53045)		BROOKFIELD WI	53008
007547	WESTERN WATER MANAGEMENT, INC.		
1345 TAMEY BOX 7469		NO KANSAS CITY MO	64116
007616	CHEM LAB PRODUCTS INC		
5160 E. AIRPORT DR.		ONTARIO CA	91761
007643	NU WAY PRODUCTS COMPANY		
220 GARRISON BOX 1508		W MEMPHIS AR	72301
007675	LITHIUM CORPORATION OF AMERICA		
BOX 795		BESSEMER CITY NC	28016
007726	CHEMMARK INTERNATIONAL		
635 E. CHAPMAN		ORANGE CA	92666
007870	HAWKINS CHEM INC		
3100 E HENNEPIN AVE		MINNEAPOLIS MN	55413
007905	LABBCO INCORPORATED		
BOX 300016		HOUSTON TX	77023
007925	THE BRITE HOUSE CO		
1050 W KINZIE ST		CHICAGO IL	60622
008033	NISSO AMERICA INC	AGENT FOR: NIPPON SODA CO LTD	
220 E 42ND ST SUITE 3002		NEW YORK NY	10017
008154	K O K CLEANSER COMPANY		
861 CAMDEN AVE		COLUMBUS OH	43201
008176	HVC INC		
4600 DUES DR		CINCINNATI OH	45246
008405	WEBCO CHEMICAL CORP		
BOX 340		WEBSTER MA	01570
008517	AMERICAN MACHINERY CORP		
PO BOX 3228		ORLANDO FL	32802
008544	GPS INDUSTRIES		
13280 A;AR RD		CITY OF INDUSTRY CA	91746
008576	HAYO CHEM COMPANY INC		
5544 OAKDALE RD		SMYRNA GA	30082
008591	MOGUL CORPORATION, THE DEXTER CORP.	D/B/A DEXTER WATER MANAGEMENT SYSTEMS DI	
BOX 200		CHAGRIN FALLS OH	44022

CO NR	CO NAME		
008616	CAVALIER CHEMICAL COMPANY INC 3901 8TH AVE	BROOKLYN NY	11232
008637	NITCO INC 1601 STEELE AVE., SW	GRAND RAPIDS MI	49507
008740	PATTERSON LABS INC 11930 PLEASANT AVE	DETROIT MI	48217
008764	FMC CORP P.O. BOX 1708	LAKELAND FL	33802
008781	METZ SALES, INC. 522 WEST FIRST STREET	WILLIAMSBURG PA	16693
008791	E-Z CLOR SYSTEMS 1920 BELTW WAY DRIVE	ST. LOUIS MO	63114
008821	NOVEL WASH COMPANY INC BOX 9981	ST LOUIS MO	63122
008866	ARCO INDUSTRIES, INC. 4871 NO. 119TH STREET	MILWAUKEE WI	53225
008873	KLEEN BRITE LAB, INC. 200 STATE STREET	BROCKPORT NY	14420
008898	WITCO CORPORATION - SH & EA 155 TICE BLVD.	WOODCLIFF LAKE NJ	07675
008996	SIERRA CHEMICAL COMPANY 2302 LARKIN CIRCLE	SPARKS NV	89431
009009	SO-WHITE CHEMICAL COMPANY 1075 PLOVER RD.	PLOVER WI	54467
009157	OLIN CORP 350 KNOTTER DR BOX 586	CHESHIRE CT	06410
009161	LAUNDRY AIDS INC 333 STARKE RD	CARLSTADT NJ	07072
009194	CENTRAZ INDUSTRIES INC 4051 BINGHAM AVENUE	ST. LOUIS MO	63116
009291	POOL TROL PRODUCTS 225 PASSAIC STREET	PASSAIC NJ	07055
009306	INDUSTRIAL SANITATION CONSULTANT P.O. BOX 1037	DANVILLE CA	94526
009336	ALLEN ENGINEERING AND CONSTRUCTION SERVICE THE BOX 613	RUTLAND VT	05701
009359	SURPASS CHEMICAL CO., INC 1254 BROADWAY	ALBANY NY	12204

CO NR	CO NAME		
009367	THEOCHEM LABORATORIES, INC.		
7373 ROWLETT PARK DRIVE		TAMPA FL	33610
009409	SARATOGA SPECIALTIES	CHEMICALS DIVISION	
150 RAILROAD AVENUE		NORTHLAKE IL	60164
009436	TEXTILE CHEMICAL COMPANY INC		
BOX 13788		READING PA	19612
009488	DELTA CHEMICAL CORPORATION		
2601 CANNERY AVE		BALTIMORE MD	21226
009594	INTECONTINENTAL CHEMICAL CORPORATION		
4660 SPRING GROVE AVENUE		CINCINNATI OH	45232
009613	BISON LABS INC		
80 LESLIE ST		BUFFALO NY	14211
009616	VERTEX CHEM CORP		
BOX 3860		ST. LOUIS MO	63122
009632	BOWMAN MELL & COMPANY		
BOX 1312		HARRISBURG PA	17105
009634	BEL AQUA POOL SUPPLY INC		
750 MAIN ST		NEW ROCHELLE NY	10805
009743	SKASOL INC		
40 CLEVELAND ST		SAN FRANCISCO CA	94103
009768	THATCHER COMPANY		
BOX 27407		SALT LAKE CITY UT	84127
009861	TECHNICAL SPECIALTIES CORPORATION		
250 ARIZONA., N.E.		ATLANTA GA	30307
010083	AMERICAN DISH SERVICE		
1016 SOUTHWEST BOULEVARD		KANSAS CITY KS	66103
010098	LERRO'S PRODUCTS INC		
1727 CARPENTER ST		PHILADELPHIA PA	19146
010147	BIRKO CORPORATION		
BOX 530		WESTMINSTER CO	80030
010182	ICI AMERICAS INC	AGRICULTURAL PRODUCTS	
NEW MURPHY ROAD & CONCORD PIKE		WILMINGTON DE	19897
010183	HAVILAND PRODUCTS COMPANY		
421 ANN ST NW		GRAND RAPIDS MI	49504
010369	ANTECH CHEMICAL COMPANY INC		
146 S MAIN ST		MIDDLETON MA	01949
010380	Q-PAK CORP		
2145 MCCARTER HWY		NEWARK NJ	07104

CO NR	CO NAME		
010477	BOND CHEMICALS, INC.		
1500 BROOKPARK RD		CLEVELAND OH	44109
010508	CHEMIDYNE CORP		
PO BOX 171		MACEDONIA OH	44056
010598	WORLD INDUSTRIES INTERNATIONAL, INC.		
17955 ARENTH AVE.		CITY OF INDUSTRY CA	91748
010613	CRYSTAL CHEMICAL & PACKING COMPANY INC		
61 VALLEY ST		WAKEFIELD MA	01880
010634	ALPHA CHEMICAL SERVICES INC		
BOX 431		STOUGHTON MA	02072
010650	MONARCH CHEMICALS, INC.		
37 MEADOW ST BOX 176		UTICA NY	13503
010663	SENTRY CHEMICAL COMPANY		
1481 ROCK MOUNTAIN BLVD		STONE MOUNTAIN GA	30086
010671	SPRINGFIELD WATER CONDITIONING COMPANY INC		
BOX 1306		SPRINGFIELD MO	65801
010876	TWINOAK PRODUCTS	DIVISION OF BLUE LUSTRE/HOME CARE PRODUC	
7950 CASTLEWAY DR		INDIANAPOLIS IN	46250
010897	HASA,INC.		
23119 DRAYTON ST.		SAUGUS CA	91350
011011	ESBRO CHEMICAL		
BOX 523		REDWOOD CITY CA	94064
011321	T-CHEM PRODUCTS DIV THURMOND CHEMICALS INC		
9028 DICE RD.		SANTA FE SPRINGS CA	90670
011411	LESLIE'S SWIMMING POOL SUPPLIES INC.		
BOX 2108		CHATSWORTH CA	91313
011611	PUMA CHEMICAL COMPANY		
3012-16 SO. MAIN ST.		FORT WORTH TX	76110
011736	COLONIAL CHEMICAL COMPANY		
CARRANZA RD-RD 3		VINCENTOWN NJ	08088
011741	DAVIES DW & COMPANY INC		
3200 PHILLIPS AVE		RACINE WI	53403
012003	BAY STATE POOL SUPPLIES INC		
26 SMITH PLACE		CAMBRIDGE MA	02138
012014	A&V INC		
N62 W22632 VILLAGE DRIVE		SUSSEX WI	53089
012465	ADVANCED LAORATORIES		
BOX 1368		WESTFIELD MA	01088

CO NR	CO NAME		
013208	WHITE HOUSE CHEM & SPLY COMPANY		
455 TRINITY AVENUE		TRENTON NJ	08619
014797	DELRAY CHEMICAL COMPANY, INC.		
1065 SW 15TH AVE., SUITE 5		DELRAY BEACH FL	33444
015265	WAUSAU CHEMICAL CORP		
BOX 953		WAUSAU WI	54401
016841	MON-D-AID & CLEANIT CO.		
143 MERCER STREET		BUTLER PA	16001
017004	PHILLIPS INDUSTRIAL PRODUCT/CROSLEY FIELD LAME		
AT 1230 FINDLAY STREET		CINCINNATI OH	45214
017705	SUPERMARKETS GENERAL CORP		
301 BLAIR ROAD		WOODBRIDGE NJ	07095
017816	GULLY POOL SERVICE & SUPPLY INC		
2757 FOWLER ST		FT MYERS FL	33901
018533	ASHLAND CHEMICAL, INC.		
BOX 2219		COLUMBUS OH	43216
018723	MIDWEST POOL SUPPLY		
7607 MURPHY DR BOX 526		MIDDLETON WI	53562
019713	DREXEL CHEMICAL COMPANY		
BOX 9306		MEMPHIS TN	38109
020474	SYRACUSE POOL CENTER		
6176 S BAY RD		CICERO NY	13039
020642	CINDY POOLS		
U S ROUTE 22		WATCHUNG NJ	07060
020719	HODGSON POOL SALES INC		
5831 SENECA ST		ELMA NY	14059
020851	PURATEX COMPANY INC THE		
6714 WAYNE AVE		PENNSAUKEN NJ	08110
021139	LCP CHEMICALS AND LCP TRANSPORTATION	DIVISION OF HAMLIN GROUP, INC.	
SOUTH WOOD AVE BOX 484		LINDEN NJ	07036
024411	HATCHICK SUPPLY CO		
5260 PORT ROYAL RD		SPRINGFIELD VA	22151
027029	CENTRAL POOL SUPPLY INC		
8211 N. DALE AVENUE		PEORIA IL	61615
027581	MIDLAND RESEARCH LAB., INC.		
10850 MID AMERICA AVENUE		LENEXA KS	66219
028690	POTOMAC CHEMICAL CORPORATION		
2916 ANNANDALE RD		FALLS CHURCH VA	22042

CO NR	CO NAME		
029443	TREAT-RITE WATER LABORATORIES INC P.O. DRAW 151	NOWATA OK	74048
029728	TWIN COUNTY GROCERS 145 TALMADGE RD	EDISON NJ	08817
032196	K.A. STEEL CHEMICALS INC 4333 TRANSWORLD RD SUITE 250	KARE CHEMICAL DIV SCHILLER PARK IL	60176
033003	GREAT WESTERN CHEMICAL COMPANY 808 S.W. 15TH STREET	PORTLAND OR	97205
033006	HUKILL CHEMICAL CORP. 7013 KRICK RD	BEDFORD OH	44146
033458	ALLIED UNIVERSAL CORP. 8350 N.W. 93 STREET	MIAMI FL	33166
033593	MARZAHL CHEMICAL COMPANY HACKENSACK AVE & 3RD ST	SO KEARNY NJ	07032
033871	SOUTHCHEM INC BOX 1491	DURHAM NC	27702
033981	K A STEEL CHEMICALS INC 4333 TRANSWORLD ROAD	SCHILLER PARK IL	60176
034093	SUNSHINE CHEMICAL SPECIALTIES, INC BOX 540	PENNSAUKEN NJ	08110
034277	PRILLAMAN CHEMICAL CORPORATION 201 SUBURBAN DRIVE BOX 1606	SUFFOLK VA	23434
034628	THE CHLORAMONE CORPORATION PO BOX 294 RIVER RD & RED LION CREEK	DELAWARE CITY DE	19706
034743	IONICS INCORPORATED 65 GROVE	WATERTOWN MA	02172
034750	THE DYCHO COMPANY BOX 513	MIOTA TN	37826
034859	WAYNE CHEMICAL INC. 7114 HOMESTEAD ROAD	FORT WAYNE IN	46804
034910	ULRICH CHEMICAL INC 3111 NORTH POST ROAD	INDIANAPOLIS IN	46226
035085	WHITE ROX CHEMICAL SOUTH MAIN ST. BOX 287	PHILLIPSBURG NJ	08865
035156	GILMER INDUSTRIES INC. BOX 1265	HARRISONBURG VA	22801
035255	BALTIMORE LAUNDRY SUPPLIES, INC. 7915 B PHILADELPHIA RD	BALTIMORE MD	21237

CO NR	CO NAME		
035317	KUEHNE CHEMICAL COMPANY, INC		
86 HACKENSACK AVE.		SOUTH KEARNY NJ	07032
035495	CHEMAX		
5700 NW FRONT AVENUE		PORTLAND OR	97210
035931	TOWN AND COUNTRY POOLS		
3773 E. MORGAN ROAD		YPSILANTI MI	48197
035934	E + E (US) INC		
2859 PACES FERRY ROAD, SUITE 1700		ATLANTA GA	30339
035949	ATLANTIC POOL MAINT., INC.		
403 SOUTH 3RD ST. - BOX 3727		LANTANA FL	33462
035984	SCOTT SWIMMING POOLS, INC		
RT. 47 WASHINGTON ROAD		WOODBURY CT	06798
036022	ACTION CHEMICAL CO INC		
1225 S 7TH ST		PHOENIX AZ	85034
036118	AMCHLOR CORPORATION		
9120 TALBOT AVENUE		SILVER SPRING MD	20910
036245	SUPERIOR CHEMICAL PRODUCT COMPANY		
220 HUBBARD ROAD		YOUNGSTOWN OH	44505
036288	ALSIP NURSERY		
12665 SOUTH CRAWFORD		ALSIP IL	60658
036404	PAZIANOS ASSOC	AGENT FOR: NISSHO IWAI AMERICAN CORP	
1338 G ST SE		WASHINGTON DC	20003
036739	SINTON SUPPLY CO., INC.		
204 E. SAMPLE STREET		SOUTH BEND IN	46618
036993	TARSON SUPPLY CORPORATION		
6071-73 EAST TAFT RD		NORTH SYRACUSE NY	13212
037062	WECHSLER CONTRACTING CO., INC		
BOX 333		MONTICELLO NY	12701
037435	C. F. POOL SUPPLIES INC		
702 COMMERCIAL DRIVE		HOLLY HILL FL	32017
037557	BARBER'S CHEMICALS, INC		
BOX 135		SHAPPSVILLE PA	16150
037621	AMERICAN BLEACH MFG CO		
1706 PORTLAND AVENUE		LOUISVILLE KY	40203
037655	WORNER EQUIPMENT OF FLA., INC		
5755 POWERLINE ROAD		FT. LAUDERDALE FL	33309
037657	J & B POOL SUPPLY		
5801 MARGATE BLVD		MARGATE FL	33063

CO NR	CO NAME		
037731	SUNCO POOL CO., INC. P.O. BOX 2186 HWY. 501 W.	MYRTLE BEACH SC	29577
037732	S&S POOL SERVICE 18265 N.E. 4TH COURT	MIAMI BEACH FL	33162
037982	ALL-PURE CHEMICAL CO 26700 S. BANTA RD - BOX 268	TRACY CA	95376
038453	CITZENS OIL COMPANY, INC. 377 PINE STREET	BURLINGTON VT	05401
038539	IMPERIAL WEST CHEMICAL CO., P.O. BOX 696	ANTIOCH CA	94509
038542	SWIFT CHEMICAL CO., INC. BOX 340	ROGERS AR	72756
038623	ROBINSON CHEMICAL CO., INC. BOX 264	CAMBRIDGE MD	21613
038699	PAT'S POOL SERVICE, INC. 5654 SWIFT ROAD	SARASOTA FL	34231
038796	ADIRONDACK CHEMICAL CORP 222 MARGARET ST BOX 892	PLATTSBURGH NY	12901
038797	MU-CLEAR POOL SERVICE, INC. 242 SOUTH REGENT STREET	PORT CHESTER NY	10573
038876	PAMPER POOL SERVICE, INC. 30 S.W. 5TH COURT	POMPANO BEACH FL	33060
039020	NOVICK CHEMICAL CO., INC. 705 DAVIS STREET	SCANTON PA	18505
039189	ENVIROCHEM INC. 317 ST. PAUL'S AVENUE	JERSEY CITY NJ	07306
039527	DADELAND POOL CO., INC. 8680 SW 137 CT.	MIAMI FL	33183
039924	UNIVERSAL CHEMICALS, INC. 100 HACKENSACK AVENUE	SOUTH KEARNY, NJ	07032
040137	PLEASURE INDUSTRIES CORP. 2179 HAIDEN LANE	ST. JOSEPH MI	49085
040702	CHEMICAL METHODS ASSOCIATES, INC. 12700 KNOTT AVENUE	GARDEN GROVE CA	92641
040703	THE WHITEX CO 155 E, BRADY ROAD	KITTANNING PA	16201
040800	EAGLE CHEMICAL CO. 125 WITMAN ROAD	READING PA	19605

CO NR	CO NAME		
040871	CHEMLAND INC.		
BOX 2999		TURLOCK CA	95381
040975	ACRO DISHWASHING SERVICE		
3 NORTH 6TH TRAFICWAY		KANSAS CITY KS	66101
041209	FEDERAL REGULATORY CONSULTANTS INC	AGENT FOR: SOUTH TEXAS CHLORINE INC	
2045 N 15TH ST SUITE 108		ARLINGTON VA	22201
041211	DX VENTURES, LIMITED PARTNERSHIP	DBA DX SYSTEMS COMPANY	
BOX 130410		HOUSTON TX	77219
041294	PRINCETON POOL & PATIO SHOP, INC.		
306 ALEXANDER ST.		PRINCETON NJ	08540
041391	BURNS CHEMICAL SYSTEMS, INC.		
3003 VENTURE COURT		EXPORT PA	15632
041394	BEAUTY POOLS, INC.		
2700 TRANSIT ROAD BOX 437		WEST SENECA NY	14224
041428	SCOTT POOL SERVICE, INC		
904 W MAIN ST		CAMEL IN	46032
041619	E.J. MILLER & SONS POOL COMPANY		
RD 4 BOX 208		MIFFLINBURG PA	17844
041702	STEELCRETE CO		
45700 W 12 MILE RD BOX 636		NOVI MI	48376
041831	PARK CORPORATION		
511 LAKE ZURICH ROAD		BARRINGTON IL	60010
041837	BLUE RIBBON POOLS, INC.		
US HIGHWAY 1 & CLINTON ST.		LINDEN NJ	07036
041934	GEORGE S. COYNE CHEMICAL CO. INC		
3015 STATE ROAD		CROYDON PA	19020
041971	NORTH INDUSTRIAL CHEMICALS, INC.		
BOX 1904		YORK PA	17405
041995	CINDERELLA INC. (CPPC)		
1215 S JEFFERSON ST		SAGINAW MI	48601
041997	DIETZ POO, INC.		
954 EAST GRAND RIVER		WILLIAMSTON MI	48895
042052	BUCKMANS POOL & SKI SHOP INC		
RT 29 RD 2 BOX 101		PERKIOMENVILLE PA	18074
042086	STRAND POOL SERVICE		
RD #3 BOX 3002		STROUDSBURG PA	18360
042177	YORK CHEMICAL CORPORATION		
3309 E CARPENTER FREEWAY		IRVING TX	75062

CO NR	CO NAME		
042233	SAHARA POOLS INC RT 22	WHITE HOUSE STATION NJ	08889
042608	ED-CHEM CORP. 16 LETSON PLACE & RT. ONE	EDISON NJ	08817
042613	INDEPENDENT CHEMICAL CO. BOX 376	PITTSTON PA	18640
042702	PATTERSON LABORATORIES,INC. 11930 PLEASANT AVE	DETROIT MI	48217
042746	MILLER ALDRIDGE CHEMICAL INC 4255 W RIVERSIDE ST	KANSAS CITY MO	64150
042895	UR INDUSTRIES INC 350 ALBANY STREET SUITE 28	NEW YORK NY	10280
043196	REK-CHEM MFG. CORP. 108 DALE SE	ALBUQUERQUE, NM	87105
043205	ATLANTIC AQUATICS P.O. BOX 417	OCEAN CITY MD	21842
043211	LANE DISTRIBUTING CORP FOOT OF CROPSEY AVE	BROOKLYN NY	11224
043216	J, L. HONBERGER CO, INC 119 BROAD ST BOX 68	SALUNGA PA	17538
043315	YARDVILLE SUPPLY CO. P.O. BOX 8427	TRENTON NJ	08650
043410	AGRI-CHEM, INC. BOX 607477	ORLANDO FL	32860
043497	PRO CHEMICALS, INC. 301 BRIDGE STREET	GREEN BAY WI	54303
043759	ABCANA CHEMICAL CO. 545 WEST BRADLEY AVE.	EL CAJON CA	92020
043882	NEW WAY CHEMICAL CO. 69 HAMDEN AVE.	GRAND CITY, STATEN ISLAND NY	10306
043922	CHEM-BRIGHT INDUSTRIES, INC. 12336 EMERSON DR	BRIGHTON MI	48116
044130	SUN POOLS, SUPPLIES & SERVICES, INC. 261 RT.,22	GREEN BROOK NJ	08812
044281	RECREATIONAL FACTORY WAREHOUSE OF ORLANDO 6325 N. ORANGE BLOSSOM TRAIL	ORLANDO FL	32810
044282	GERALD A. JESSE 1105 MAIN ST.	SWIM WELL PRODUCTS TAYLOR PA	18517

CO NR	CO NAME		
044628	WATERSCIENCE, INC. 175 MEISTER AVENUE	SOMERVILLE NJ	08876
044751	NATIONAL SAFETY ASSOCIATES, INC 4260 EAST RAINES ROAD	MEMPHIS TN	38118
044917	VALUE PRODUCTS, INC. 2765 SCOTT BLVD.	SANTA CLARA CA	95050
045159	MOBILE WATER TECHNOLOGY BOX 14867	MEMPHIS TN	38114
045225	ENVIROTECH OPERATING SEVICES 5500 HOUCHIN STREET	NAPLES FL	33942
045309	AQUA CLEAR INDUSTRIES, INC. 20 KAIRNES STREET BOX 5430	ALBANY NY	12205
045387	SCIENTIFIC WATER SYSTEMS BOX 52886	LAFAYETTE LA	70505
045447	CLENESCO PRODUCTS CORP. 298 COX STREET	ROSELLE NJ	07203
045458	BALECO INTERNATIONAL INC BOX 11035	CINCINNATI OH	45211
045655	HIGH-PO-CHLOR, INC. BOX 410	CHELSEA MI	48118
045720	SMITH CHEMICAL CORP. 1221 THIRD STREET NE	CANTON OH	44704
045983	JET INC. 750 ALPHA DRIVE	CLEVELAND OH	44143
046183	SAFEWAY INDUSTRIES, INC. 3372 N. HOLTON STREET	MILWAUKEE WI	53212
046270	BENBOW CHEMICAL PACKAGING INC. 935 EAST HIAWATHA BLVD.	SYRACUSE NY	13208
046372	WATER ENGINEERING SERVICES 22 EAST BUCHANAN STREET	PHOENIX AZ	85004
046506	BIONOX CO., INC. 6890 E. LOMA DEL BRIBON	TUCZO AZ	85715
046554	REACTIVE METALS & ALLOYS CORPORATION RT 168 ; BOX 366	WEST PITTSBURG PA	16160
046854	G.M. GANNON CO., INC. 3134 POST RD.	WARWICK RI	02887
047033	CASCADE WATER SERVICES INC. 49 BLOOMINGDALE ROAD	HICKSVILLE NY	11801

CO NR	CO NAME		
047230	ENTERPRISE CHEMICAL CO.		
12700 KNOTT AVENUE		GARDEN GROVE CA	92641
047250	AQUA BLUE POOLS OF CENTRAL FLORIDA, INC.		
1132 SOUTH PATRICK DR.		SATELLITE BEACH FL	32937
047368	NORD LABORATORIES		
419 ORTO STREET		SAN JOSE CA	95125
048211	INTERCON CHEMICAL		
3647 BELL AVENUE		ST. LOUIS MO	63108
048226	CHEMICAL POOLS		
477 N COURTENAY PKWY BOX 540056		MERRITT IS FL	32954
048242	RAN CHEMICAL & SUPPLY		
9836 CLAY RD.		HOUSTON TX	77080
048482	EES CORPORATION	AN ELTECH SYSTEMS CO	
12850 BOURNEWOOD DR		SUGAR LAND TX	77478
048520	PHOENIX CHEMICAL CO		
8 FAIRFIELD COURT		DANBURY CT	06811
049337	YARNELL POOL SUPPLY		
3461 PENNELL RD -RT 452		MEDRA PA	19063
049592	APPLIED METHODS ENTERPRISES INC		
100 SIWANOY BLVD		EASTCHESTER NY	10707
049614	CK ENTERPRISES		
463 SE OLDHAM PARKWAY		LEE'S SUMMIT MO	64063
049927	WATER GUARD, INC.		
BOX 2226		WILSON NC	27893
050416	PROCLEAN SYSTEMS INC		
4600 FLAT ROCK ROAD		PHILADELPHIA PA	19127
050431	NORTH FLORIDA WATER TREATMENT, INC.		
387-SAN MARCO AVE.		ST. AUGUSTINE FL	32084
050510	AUTOTROL CORP.		
5730 NORTH GLEN PARK ROAD		MILWAUKEE WI	53209
050566	WESLEY WATER CHEMICALS		
BOX 490		MONTROSE AL	36559
050956	MR. GEORGE DYCHDALA	AGENT FOR: SASKATOON CHEMICALS LTD	
68 SHIRLEY LN		NORRISTOWN PA	19403
051014	GUARD-RITE CHEMICALS INC.		
5216 CHAKEMCO		SOUTH GATE CA	90280
051185	MANN POOL CO.		
333 W. MAPLE-RT30		NEW LENOX IL	60451

CO NR	CO NAME		
051354	G & S ENTERPRISES 8957 E. CENTRA AVENUE	CARLISLE OH	45005
051549	U.S. CHLORINE, INC. 5675 NW 36TH AVE.	MIAMI FL	33142
051790	COASTAL CHEMICAL CO. 75 GEORGIA PACIFIC WAY BOX 456	HAMPTON GA	30228
052341	KAL CHEMICALS, INC. 4620 N. LARKIN DR.	COVINA CA	91722
052374	SUMMIT INDUSTRIES 5702 E. CHANNEL ROAD	DIVISION OF ADVANCE CHEMICAL DISTRIBUTI CATOOSA OK	74015
052483	H KREVIT AND CO., INC. BOX 9433	NEW HAVEN CT	06534
053026	B & B CHLORINATION CO. P.O. BOX 246	ALBERT CITY IA	50510
053257	CLEARWATER CHEMICAL CORP. 1575 SUNSHINE DR.	CLEARWATER FL	34625
053569	CHEM WEST 8015 DEERING AVENUE	CANOGA PARK CA	91304
054521	ENTERPRISE SOLUTIONS 974 EXPLORERS COVE #124	ALTAMONTE SPRINGS FL	32701
054536	RICHARD'S HARDWARE 7041 TAFT ST.	HOLLYWOOD FL	33024
054679	CUSTOM CONTROLS & PUMPS INC 3816 NE 40TH PL	OCALA FL	32670
054739	CMA OF OHIO INCORPORATED 3924 CLEVELAND AVE. NW	CANTON OH	44709
054998	CAPO INDUSTRIES, LTD. 900 HERTEL AVENUE BOX 209	BUFFALO NY	14206
055304	KRUDICO INC. 308 E 4TH	AUBURN IA	51433
055487	B'S POOL SUPPLIES 2081 HELLMAN AVE UNIT J	ONTARIO CA	91761
055714	AQUA SPECIALISTS INC. 160 SILVER PRING RD. BOX 123	MECHANICSBURG PA	17055
055736	PRAIRIE INDUSTRIAL CHEMICALS, INC BOX 2219	WILLISTON ND	58802
056003	AQUA CHEMICAL SALES & DELIVERY, INC. 1412 JOLIET RD BOX 609	LEMONT IL	60439

CO NR	CO NAME		
056138	SAFE-GUARD CHEMICALS CO.		
2212 1/2 NORTH CHICO AVENUE		SOUTH ELMONTE CA	91733
056281	AQUA SYSTEMS, INC		
BOX 397		ARROYO GRANDE CA	93421
056392	CALTECH INDUSTRIES INC		
BOX 1139		MIDLAND MI	48640
056452	POOL WATER PRODUCTS		
17872 MITCHELL BOX 17359		IRVINE CA	92713
056618	AMREX CHEMICAL CORP		
117 E. FREDERICK ST. BOX 642		BINGHAMTON NY	13902
056845	CARDINAL CHEMICAL CORP.		
BOX 248		LEMONT IL	60439
056899	RMI TITANIUM CO - SODIUM PLANT	(AN OHIO CORPORATION)	
BOX 269		NILES OH	44446
057125	THE DIAL CORPORATION	TECHNICAL CENTER	
15101 NORTH SCOTTSDALE ROAD		SCOTTSDALE AZ	85254
057159	NORTH COUNTRY DAIRY SUPPLY, INC		
BOX 26		WESTRUTLAND VT	05777
057351	SUNBELT CHEMICALS, INC		
71 HARGROVE GRADE		PALM COAST FL	32137
057425	EUGENE P. DEATRICK	AGENT FOR: CONTROL CHEMICALS (PTY) LTD.	
1013 EAST TAYLOR RUN PARKWAY		ALEXANDRIA VA	22302
057586	KENWOOD POOLS & SPAS		
8522 NEW FALLS ROAD		LEVITTOWN PA	19054
057787	HAVILAND CONSUMER PRODUCTS, INC.		
1855 TURNER AVENUE, NW		GRAND RAPIDS MI	49504
057856	NEWBY OIL WAREHOUSE OUTLET		
2270 OAKLAND DRIVE		SYCAMORE IL	60178
058648	BRITE MANUFACTURING COMPANY, INC.		
1501 ST. LOUIS STREET		NEW ORLEANS LA	70112
059074	SLACK CHEMICAL CO.,INC.		
465 SO. CLINTON ST		CARTHAGE NY	13619
059151	NUCHEM CORPORATION		
2900 WM.,PENN HIGHWAY BOX 3369		PALMER PA	18043
059198	VIKING CHEMICAL CO.		
BOX 1595		ROCKFORD IL	61110
059289	LOCKWOOD LABORATORIES INC.		
2830 - 169TH ST		HAMMOND IN	46323

CO NR	CO NAME		
059426	J. JAMES SMULLEN, INC		
505 EAST MAIN STREET		SALISBURY MD	21801
059623	SEE 10964 CALIF. DEPT. OF FOOD & AGRI.		
1220 N ST		SACRAMENTO CA	95814
059715	E.S. FIREPLACE STORE, INC.		
R.D. #8 BOX 257		KITTANNING PA	16201
059893	COUSTIC-GLO INTERNATIONAL, INC.		
7111 OHMS LANE		MINNEAPOLIS MN	55435
060211	HAWAII ASSOCIATION OF NURSERYMEN		
BOX 293		HONOLULU HI	96809
061428	7C'S SAFETY AND ENVIRONMENTAL CONSULTANTS		
5901 WARNER AVE		HUNTINGTON BEACH CA	92649
061602	LAROCHE CHEMICALS INC.		
BOX 1031		BATON ROUGE LA	70821
062032	ACCU-CARE SUPPLY, INC.		
1190 BROAD ST.		PROVIDENCE RI	02905
062207	FOX PACKAGING, INC.		
51 E MARYLAND AVE		ST. PAUL MN	55117
062341	FEDERAL REGULATORY CONSULTANTS, INC	AGENT FOR: TRINITY MANUFACTURING, INC	
2045 N 15TH ST SUITE 108		ARLINGTON VA	22201
062495	THE EXCELEX CORPORATION		
2929 STOREY LANE		DALLAS TX	75220
062550	ENICHEM AMERICAS INC.	AGENT FOR: SANATEC	
1211 AVENUE OF THE AMERICAS INC.		NEW YORK NY	10036
063231	BEAR CREEK PRODUCTION CO.		
BOX 280		WASCO CA	93280
063243	NORWALK WASTEWATER EQUIPMENT CO.		
220 REPUBLIC ST.		NORWALK OH	44857
063404	TIDEWATER INDUSTRIAL CORPORATION		
BOX 491		GREENSBORO MD	21639
063823	MANAGEMENT CONTRACT SERVICES, INC.		
BOX 5209		VALDOSTA GA	31603
063824	EXSL/ULTRA LABS, INC.		
1767 NA.IONAL AVENUE		HAYWARD CA	94545
065268	ROGERS NK SEED CO		
BOX 4727		BOISE ID	83711

Records printed: 378

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORM FORMS

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 Approval Expires 12-31-92

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

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

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are:

   _____

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D)

Signature	Date
Name and Title (Please Type or Print)	