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Office of Prevention, Pesticides
And Toxic Substances
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Reregistration Eligibility Document (RED)

Alkyl Amine Hydrochloride

REREGISTRATION ELIGIBILITY DOCUMENT

Alkyl amine hydrochloride

LIST C

CASE 3051

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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VI. APPENDICES

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
Agency	U.S. Environmental Protection Agency
CAS	Chemical Abstracts Service
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
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.
LOAEL	Lowest observable adverse effect level
MUP	Manufacturing Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
ppm	Parts per Million
RED	Reregistration Eligibility Document

EXECUTIVE SUMMARY

This Reregistration Eligibility Document addresses pesticide uses of alkyl amine hydrochloride. Alkyl amine hydrochloride products are currently registered for use in hospitals both human and veterinary and in commercial and industrial premises as a bacteriocide/ bacteriostat, microbicide/microbiostat and fungicide. It also is added to adhesives, paints and emulsions as a preservative. All products containing alkyl amine hydrochloride as an active ingredient are eligible for reregistration.

The Environmental Protection Agency (EPA) has conducted a review of the scientific data base and other relevant information supporting the reregistration of alkyl amine hydrochloride and has determined that the data base is substantially complete and sufficient to allow EPA to conduct a reasonable risk assessment.

The data available to the EPA supports the conclusion that the currently registered uses of alkyl amine hydrochloride will not result in unreasonable adverse effects to the environment or human health.

Accordingly, EPA has determined that the registered uses of alkyl amine hydrochloride are eligible for reregistration. The decision to reregister specific products will be made after appropriate labeling and product specific data are submitted and/or cited. Before reregistering each product, the EPA is requiring that product specific data and revised labeling be submitted by the registrants within eight months of the issuance of this document. After reviewing these data and labels, the EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product labeling and composition are acceptable and their uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met, EPA will reregister the products. 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.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" 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 alkyl amine hydrochloride. The document consists of six sections. Section I is the introduction. Section II describes alkyl amine hydrochloride, its uses, data requirements 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 alkyl amine hydrochloride. Section V discusses the reregistration requirements for alkyl amine hydrochloride. Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1] EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

Chemical Name: ρ-alkyl amine hydrochloride (as in fatty acids of coconut)

CAS Registry Number: 929-73-7

Office of Pesticide Programs Chemical Code: 069152

Empirical Formula: $C_{12}H_{27}NHCl$

Molecular Weight: 221.82

B. Use Profile

The following is information on the registered use with specific use sites and application methods. A detailed table of eligible uses of alkyl amine hydrochloride is in Appendix A.

Type of Pesticide:	bacteriocide/bacteriostat, microbicide/microbiostat, fungicide, preservative, self-sanitizer
Use Sites:	INDOOR MEDICAL: Hospital/medical institutions premises - human/veterinary INDOOR NONFOOD: Commercial/institutional/industrial premises/equipment (indoor); adhesives; industrial (preservatives); latex paints (in-can) (preservatives); emulsions, resin/latex/polymer (additives/preservatives) INDOOR RESIDENTIAL: Household/domestic dwellings
Pests:	Deterioration/spoilage bacteria, including Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Fungi (mildew)
Formulation Types Registered:	Liquid - ready to use, soluble concentrate/liquid

Method and Rates of Application: TYPES OF TREATMENT: Industrial preservative, mop

Equipment: Spray, mop

C. Regulatory History

A product containing alkyl amine hydrochloride, was first registered in 1971. Since then, two other products have been registered. Alkyl amine hydrochloride products are used as a self-sanitizer for floors and equipment and as a preservative in paints and other coatings. Since there are no uses associated with human foods or animal feeds, there are no established tolerances for residues of alkyl amine hydrochloride.

III. SCIENCE ASSESSMENT OF ALKYL AMINE HYDROCHLORIDE

The Agency has conducted a review of the scientific data base for alkyl amine hydrochloride. The findings are summarized below.

A. DESCRIPTION OF ACTIVE INGREDIENT

Two analytical procedures were developed by Huls America, Inc. Both methods are filed under MRID 41671201. One method determines the active ingredient, ρ-alkyl amine hydrochloride, and the second determines an inert solvent.

Alkyl amine hydrochloride, the salt of coconut oil fatty acids, is a crystalline free flowing solid of straw yellow color with very little odor. It has a water solubility of 44.5 gm/100 ml and an octanol solubility of 4.67 gm/100 ml. It has a specific gravity of 0.975, a vapor pressure of 1×10^{-5} Torr, and an octanol/water partition coefficient of 11 ± 3. Its melting point is 164-170° C, its dissociation constant (pK_a) is 2.3, and its pH is 6.31. It is stable to hydrolysis and metabolism over the short term.

B. HUMAN HEALTH ASSESSMENT

The Agency has determined that sufficient data have been submitted to assess the potential health hazards, exposures and risks from the current registered pesticide uses of alkyl amine hydrochloride.

1. Toxicology

a. Acute Toxicity

ACUTE TOXICITY VALUES

TEST	RESULT (mg/kg)	CATEGORY
Oral LD_{50}	1058 mg/kg	III
Inhalation LC_{50}	Waived	I*
Dermal LD_{50}	> 2000 mg/kg	III
Eye effects	Waived	I*
Skin effects	Corrosive	I*
Dermal Sensitization	mild to strong	N/A**

* Category based on corrosiveness shown in dermal testing.
** Not applicable

b. Subchronic Toxicity

A repeat dose dermal 90-day toxicity study was conducted in rats. Animals received alkyl amine hydrochloride at doses of 0, 50 or 125 mg/kg/day for 13 weeks. The systemic NOEL was 50 mg/kg/day and the systemic LOEL was 125 mg/kg/day based on the presence of an inflammatory skin response and a reported increase in adrenal weights (MRID 41735501).

c. Chronic Toxicity

Alkyl amine hydrochloride was administered at doses of 0, 25, 75 or 150 mg/kg/day to pregnant rats on days 6 through 15 of gestation. At the 25 mg/kg/day dose, the compound had no effect on maternal animals. The maternal LOEL was determined to be 75 mg/kg/day based on observations of decreased body weight and decreased food consumption which occurred during the treatment period. The NOEL for developmental toxicity was 75 mg/kg/day and the developmental LOAEL was 150 mg/kg/day based on increased post-implantation loss and decreased fetal body weight. However, the Agency believes these effects were secondary to the maternal toxicity at the highest dose tested. No developmental malformations or variations were observed which could be related to the administration of alkyl amine hydrochloride. (MRID 41537601 and 41537602).

d. Mutagenicity

Alkyl amine hydrochloride has not shown genetic toxicity. The compound was negative for gene mutations (MRID 41287101), structural chromosome aberrations (MRID 41287103) and unscheduled DNA synthesis (MRID 41287102).

2. Dietary Exposure

There are no registered food uses for alkyl amine hydrochloride. As an antimicrobial constituent of liquid floor wax and industrial coatings, the substance has no uses which would bring it into contact with food. Consequently, tolerances have not been established.

3. Occupational Exposure

Occupational exposure to alkyl amine hydrochloride results from the uses of the liquid floor wax (hand mop application) and the industrial preservative in paints, adhesives and coatings. The floor wax product contains 0.063 percent active ingredient of the antimicrobial. One of the two industrial preservative products contains 25 percent alkyl amine hydrochloride and the other, 21.2 percent. These products are incorporated during the manufacturing process of paints, adhesives and coatings.

Applicator exposure to the antimicrobial would result from the floor-mop application of the floor wax products or the manufacture of industrial coatings. The floor wax product labels instruct applicators to get medical attention if skin irritation develops.

From the industrial use application, there is a potential for eye, dermal and inhalation exposure to workers in the coatings industry. Technical alkyl amine hydrochloride is in Category I for inhalation, eye and dermal irritation. However, labels instruct users to wear eye shields, rubber gloves, respirator and protective clothing to mitigate exposure.

The Agency has determined that, when used as directed on the labels, alkyl amine hydrochloride exposure will be minimal.

4. Human Risk Assessment

The toxicology studies on alkyl amine hydrochloride and information about its uses are sufficient for assessing potential human risk.

Although the acute oral and dermal toxicities are in Category III, alkyl amine hydrochloride is corrosive (Category I) to the skin and, therefore, also likely to be corrosive to the eyes and lungs. At 125 mg/kg/day, subchronic dermal testing (rats) shows increased adrenal weights and an inflammatory skin response. In a developmental toxicity study, also in rats, the developmental LOAEL was 150 mg/kg/day, based on post-implantation loss and decreased fetal weight, with no malformations or variations at any dose. Decreased maternal body weight occurred at lower dose level, 75 mg/kg/day. Because these effects likely were caused by maternal toxicity as stated above, the Agency believes this does not constitute a concern for unreasonable risks to workers.

Mutagenicity was not observed for alkyl amine hydrochloride in separate assays for gene mutations, chromosomal aberrations, or unscheduled DNA synthesis.

Toxicological and exposure data are adequate for alkyl amine hydrochloride. Prudent use should not result in any unreasonable hazard. In view of the adequacy of the toxicological data for alkyl amine hydrochloride, there are no significant exposure concerns other than providing assurance that the formulated concentrates of this corrosive ingredient contain proper cautionary statements as addressed in section IV, C.

C. ENVIRONMENTAL ASSESSMENT

1. Environmental Fate Assessment

Alkyl amine hydrochloride is a mixture of closely related compounds of the general class of quaternary amines. Diluted in water, it is expected to remain stable to hydrolysis and degradation over the short term. In time, the compound would be expected to undergo microbial metabolism, yielding such metabolites as ammonia, chloride, short(er) chain fatty acids, and finally CO_2. The use is limited to the inside of buildings which restricts its presence from exterior environments. For this reason, the Agency is not requiring any environmental chemistry data at this time. The only data the Agency would ordinarily ask for is hydrolysis, which is required for all registered pesticides regardless of use pattern. However, in this case, a thirty-day hydrolysis study would not be likely to yield any useful information, since little or no hydrolysis would be expected to take place.

2. Ecological Effects Assessment

The Agency has reviewed four basic ecotoxicology studies for alkyl amine hydrochloride. The Agency's conclusions for the avian and aquatic effects studies follows.

a. Terrestrial Studies

Alkyl amine hydrochloride is considered to be slightly toxic to upland game birds and waterfowl with an acute oral LD_{50} value of 989 mg/kg (MRID 41671701). The avian dietary study gave LD_{50} values > 5620 ppm. Based on this information, the chemical is categorized as practically nontoxic through dietary exposure to upland game birds and waterfowl.

b. Aquatic Studies

Two studies were performed to assess aquatic toxicity. Based on rainbow trout and Daphnia testing, alkyl amine hydrochloride is classified as highly toxic to freshwater fish with LC_{50} values of 0.18 ppm and 0.48 ppm, and very highly toxic to freshwater invertebrates with LC_{50} = 0.01 ppm.

3. Ecological Effects Risk Assessment

Although some of the studies were deficient in their conduct, they are adequate to provide the Agency with sufficient information to determine appropriate label precautions. These label precautions are included in IV. C. Labeling Requirements For Products Containing Alkyl Amine Hydrochloride.

No risk assessment was performed for alkyl amine hydrochloride, given the expectation of no exterior exposure from its indoor use.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR ALKYL AMINE HYDROCHLORIDE

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 previously has identified and required or waived the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing alkyl amine hydrochloride as an active ingredient. The Agency has completed its review of these generic data and information from published literature, and has determined that the data are sufficient to support reregistration

of products containing alkyl amine hydrochloride. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of alkyl amine hydrochloride, 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 alkyl amine hydrochloride. The data available to the Agency support the belief that the registered uses of alkyl amine hydrochloride will not result in unreasonable adverse effects to human health or the environment. The Agency has determined that all products containing alkyl amine hydrochloride as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in section V of this document ("Product Reregistration").

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, various articles available in the public literature which are identified in Appendix C and the data identified in Appendix B. Although the Agency has found that products containing alkyl amine hydrochloride 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 alkyl amine hydrochloride 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 alkyl amine hydrochloride has been reviewed and determined to be complete.

C. LABELING REQUIREMENTS FOR ALKYL AMINE HYDROCHLORIDE PRODUCTS

Products labeled for" manufacturing use only as a preservative" must delete the word "manufacturing" in the Directions for Use section of the label. Labels on these products state that "concentrated solutions are corrosive and cause severe eye and skin damage." Therefore, labeling for these products must include the requirement for the use of eye shields, rubber gloves, a pesticide respirator and protective clothing. The label must carry the skull and crossbones along with the word "poison" because products with alkyl amine hydrochloride are classified Category I for the inhalation route of exposure. The Precautionary Statements section on all labels must include the statement "prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

1. LABELING REQUIREMENTS FOR INDUSTRIAL PRESERVATIVE PRODUCTS

Products labeled for uses as an industrial preservative must contain the following warning in the Environmental Hazards section of the label: "This pesticide is toxic to fish and aquatic invertebrates. 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 this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of U.S. EPA."

2. LABELING REQUIREMENTS FOR FLOOR WAX PRODUCTS

Products labeled for use in floor wax formulations must contain "Avoid contamination of foods" in the Directions for Use section of the product label.

V. ACTIONS REQUIRED BY REGISTRANTS OF END-USE PRODUCTS

A. DETERMINATION OF ELIGIBILITY

The active ingredient alkyl amine hydrochloride and the products containing it are eligible for reregistration based on the reviews of the generic data. 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.

1. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are stated in Attachment C.

2. LABELING REQUIREMENTS FOR END-USE PRODUCTS

The labels and labeling of all products must comply with the Agency's current regulations and requirements. Follow the instructions in Section IV. and in the Product Reregistration Handbook with respect to labels and labeling.

APPENDIX A

Alkyl Amine Hydrochloride Use Patterns Subject to Reregistration

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR (COCO ALKYL)AMINE HYDROCHLORIDE

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Apps	Max. # Apps @ Max. Rate (Days)	Minimum Interval Between Apps. @ Max (Days)	Restricted Interval (Days)	Geographic Limitations	Use Limitation (code)
NON-FOOD/NON-FEED USES - ELIGIBLE FOR REREGISTRATION									
ADHESIVES, INDUSTRIAL Use Group(s): INDOOR NON-FOOD									
Preservative treatment, During manufacturing, Not on label	FM/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Preservative treatment, During manufacturing, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
EMULSIONS, RESIN/LATEX/POLYMER Use Group(s): INDOOR NON-FOOD									
Preservative treatment, During manufacturing, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
PAINTS, LATEX (IN-CAN) Use Group(s): INDOOR NON-FOOD									
Preservative treatment, During manufacturing, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
FLOORS (UNSPECIFIED) Use Group(s): INDOOR MEDICAL, INDOOR NON-FOOD, and INDOOR RESIDENTIAL									
Mop, Not on label, Mop	RTU	na	Dose cannot be calculated	Not spec	Not spec	Not spec	Not Spec	None	A08

Abbreviations used

Header:

max=maximum; min=minimum; apps=applications; not spec=not specified; na=not applicable

Form:

RTU=ready-to-use; SC/L=soluble concentrate/liquid; FM/L=formulation not identified/liquid

Use Limitation:

A08=preclean claim

APPENDIX B

Generic Data Requirements for Reregistration of Alkyl Amine Hydrochloride 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 tables generally are 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 letter designation M is used for the indoor nonfood use pattern associated with alkyl amine hydrochloride.

3. Bibliographic citation (Column 3). If the EPA 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 ALKYL AMINE HYDROCHLORIDE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Chemical identity	M	42313101
61-2(a)	Begining material and manufacturing process	M	41671201
61-2(b)	Discussion of Impurities	M	41671201
62-1	Preliminary analysis	M	41671202
62-2	Certification of limits	M	41671202
62-3	Analytical method	M	41671202
63-2	Color	M	41671203
63-3	Physical state	M	42332601
63-4	Odor	M	41671203
63-5	Melting point	M	42332601
63-7	Density	M	41671203
63-8	Solubility	M	42313102

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF ALKYL AMINE HYDROCHLORIDE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry cont'd			
63-9	Vapor pressure	M	41671203
63-10	Dissociation constant	M	41671203
63-11	Octonal/water partition	M	41671203
63-12	pH	M	41671203
63-13	Stability	M	41671203
Ecological Effects			
71-1(a)	Acute avian oral - quail	M	41671701
71-2(a)	Acute avian dietary - quail	M	41671702
71-2(a)	Acute avian dietary - duck	M	41671709
72-1(a)	Fish toxicity - Bluegill	M	41671710
72-1(b)	Fish toxicity - Rainbow Trout	M	41671703
72-2(a)	Invertebrate toxicity	M	41671704

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF ALKYL AMINE HYDROCHLORIDE AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology			
81-1	Acute oral tox - rat	M	416717-05
81-2	Acute dermal tox - rabbit	M	416717-06
81-5	Primary dermal irritation - rabbit	M	416717-07
81-6	Dermal sensitization	M	416717-08
82-2	21-day dermal - rabbit	M	421343-01
82-3	90-day dermal - rodent	M	417355-01
83-3(a)	Teratogenicity - rat	M	415376-01 415376-02
84-2(a)	Gene mutation - Ames	M	412871-01
84-2(b)	Structural chromosome	M	412871-03
84-4	Other genotoxic effects	M	412871-02

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Alkyl Amine Hydrochloride

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

1.CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all publications considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for published literature in this bibliography have been the body of data submitted to EPA in support of past regulatory decisions.

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 also is to be used whenever specific reference is needed.

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

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

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

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

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

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

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

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

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

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
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APPENDIX D

PR Notice 91-2

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

PR NOTICE 91-2

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

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).

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

APPENDIX E

Pesticide Reregistration Handbook

APPENDIX F

Product Specific Data Call-In

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

DATA CALL-IN NOTICE

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

CERTIFIED MAIL

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).

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, all of the following three criteria must be clearly met:

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 (Attachment E) 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 EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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.

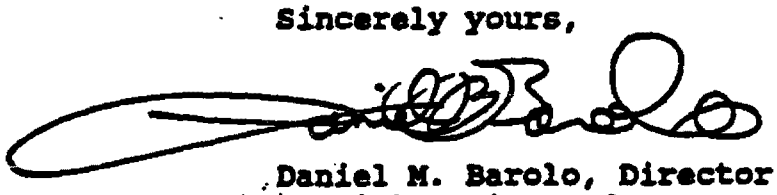
SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

Chemical Status Sheet

ATTACHMENT A

ALKYL AMINE HYDROCHLORIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing alkyl amine hydrochloride.

This attachment, the Data Call-in Chemical Status Sheet, contains a 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 Alkyl Amine Hydrochloride Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The Agency has concluded that product specific data are needed for alkyl amine hydrochloride. 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 Karen Leavy at (703) 305-6966. All responses to this Notice should be submitted to:

Document Processing Desk (RED/RD/PM-31)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Alkyl amine hydrochloride

If you have any questions regarding this Notice, please contact Betty Crompton at (703) 308-8067. All responses to this Notice should be submitted to:

Chemical Review Manager Betty Crompton
Accelerated Reregistration Branch (H7508W)
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Alkyl amine hydrochloride

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

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
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts	PRODUCT SPECIFIC

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."
1100-84		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

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
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts	PRODUCT SPECIFIC

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."
1100-85		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

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
CARROLL COMPANY 2900 W. KINGSLEY RD. GARLAND TX 75041	3051 (Coco alkyl)amine salts	PRODUCT SPECIFIC

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."
4313-37		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 (FORMS B) PLUS INSTRUCTIONS AND PR NOTICE 86-5

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	3. Date and Type of DCI
CARROLL COMPANY 2900 W. KINGSLEY RD. GARLAND TX 75041	3051 (Coco alkyl)amine salts EPA Reg. No. 4313-37	PRODUCT SPECIFIC ID# 4313-RD-1910

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	EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	EP	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

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-9

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
CARROLL COMPANY 2900 W. KINGSLEY RD. GARLAND TX 75041	3051 (Coco alkyl)amine salts EPA Reg. No. 4313-37	PRODUCT SPECIFIC ID# 4313-RD-1910

4. Guideline Requirement Number	5. Study Title		Reqd	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-17	Storage stability	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	EP	8 mos.	
63-21	Dielectric breakdown voltage	(16)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Efficacy - Antimicrobial Agents - Public Health Uses									
	Miscellaneous Indoor Hard									

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	3. Date and Type of DCI
CARROLL COMPANY 2900 W. KINGSLEY RD. GARLAND TX 75041	3051 (Coco alkyl)amine salts EPA Reg. No. 4313-37	PRODUCT SPECIFIC ID# 4313-RD-1910

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
	Surfaces								
91-2	Self-sanitizing test (1,2)					LMNO	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

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 3051 (Coco alkyl)amine salts

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
001100	HULS AMERICA, INC.		BOX 365	PISCATAWAY NJ	08855
004313	CARROLL COMPANY		2900 W. KINGSLEY RD.	GARLAND TX	75041

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	3. Date and Type of DCI
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-84	PRODUCT SPECIFIC ID# 1100-RD-1908

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	EP	8 mos.	
61-2(a)	Descrip of starting materials (1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
	production & formulation proc								
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	EP	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

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
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-84	PRODUCT SPECIFIC ID# 1100-RD-1908

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
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-17	Storage stability	(15)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	EP	8 mos.	
63-21	Dielectric breakdown voltage	(16)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Efficacy - Antimicrobial Agents - Public Health Uses									
	Miscellaneous Indoor Hard									

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	3. Date and Type of DCI
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-84	PRODUCT SPECIFIC ID# 1100-RD-1908

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
91-2	Surface Self-sanitizing test (1,2)					LMNO	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	3. Date and Type of DCI
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-85	PRODUCT SPECIFIC ID# 1100-RD-1909

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	EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	EP	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

Form Approved
OMB No. 2070-0107
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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
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-85	PRODUCT SPECIFIC ID# 1100-RD-1909

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
63-15	Flammability (11)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-17	Storage stability (15)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	EP	8 mos.	
63-21	Dielectric breakdown voltage (16)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,36,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Efficacy - Antimicrobial Agents - Public Health Uses								
	Miscellaneous Indoor Hard								

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	3. Date and Type of DCI
HULS AMERICA, INC. BOX 365 PISCATAWAY NJ 08855	3051 (Coco alkyl)amine salts EPA Reg. No. 1100-85	PRODUCT SPECIFIC ID# 1100-RD-1909

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
	Surfaces								
91-2	Self-sanitizing test (1,2)					LMNO	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: 3051 (Coco alkyl)amine salts

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or 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: *158.153 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.
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.
16 Basic manufactures are required to provide the Agency with a sample of each TGAI used to formulate a product when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis. Material safety data sheets should accompany samples as specified by OSHA in 29 CFR 1910.1200.

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

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3051 (Coco alkyl)amine salts

Footnotes (cont.):

of potential eye and dermal irritation effects.

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.

36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Efficacy - Antimicrobial Agent

1 Efficacy data for antimicrobial agents that claim to control pest microorganisms that may pose a threat to human must be submitted.

2 Comparative product performance data are required to be developed and maintained in the registrant's file and must be submitted to the Agency on a case-by-case basis for risk/benefit analyses such as for public interest findings and cases of special review.

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 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.

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 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 requirement 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 make 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.

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 antoher 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

JUL 29 1986

PR NOTICE 86-5

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX -

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A. Organization of Submittal Package

A 'submittal package' consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to <u>one</u> study, they should be included as an appendix to that study.
- If such materials relate to <u>more than one</u> study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (ie., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study,

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed 'example' cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required.	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies. (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1 Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; DO NOT INCLUDE CBI ON THE TITLE PAGE. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the Statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c). (See Attachment 3) These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(d)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked 'Confidential Attachment.' An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.
- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.
- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5 Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (see Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the 'Supplemental Statement of Data Confidentiality Claims'.
- Remove the 'Confidential Attachment'.
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact William C. Grosse, Chief, Information Services Branch, Program Management and Support Division, (703-557-2613).

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1.

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

†Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

†Smith Chemical Corp. will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

.
.
.

Vol n. Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

** Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2.

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3.

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4.

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5.

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1 (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
28	25	"	"
100	19	"	"

Example 2 (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20	8-17	Description of the quality control process	§10(d)(1)(C)

Example 3 (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
33-41	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter _____

Sponsor _____

Study Director _____

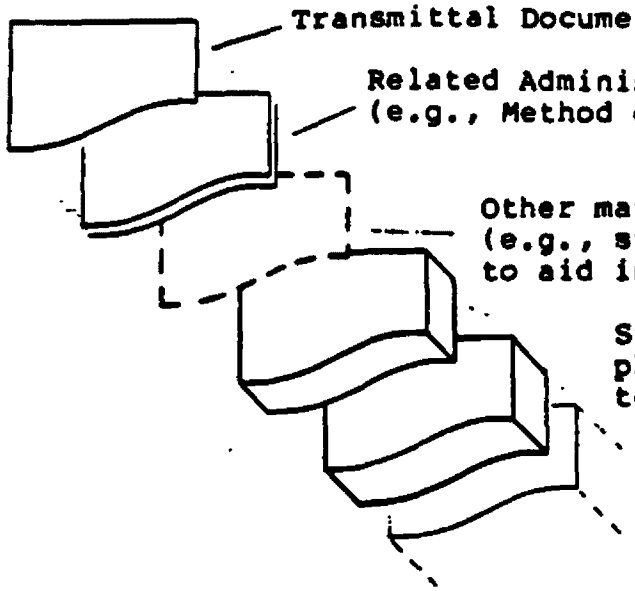
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

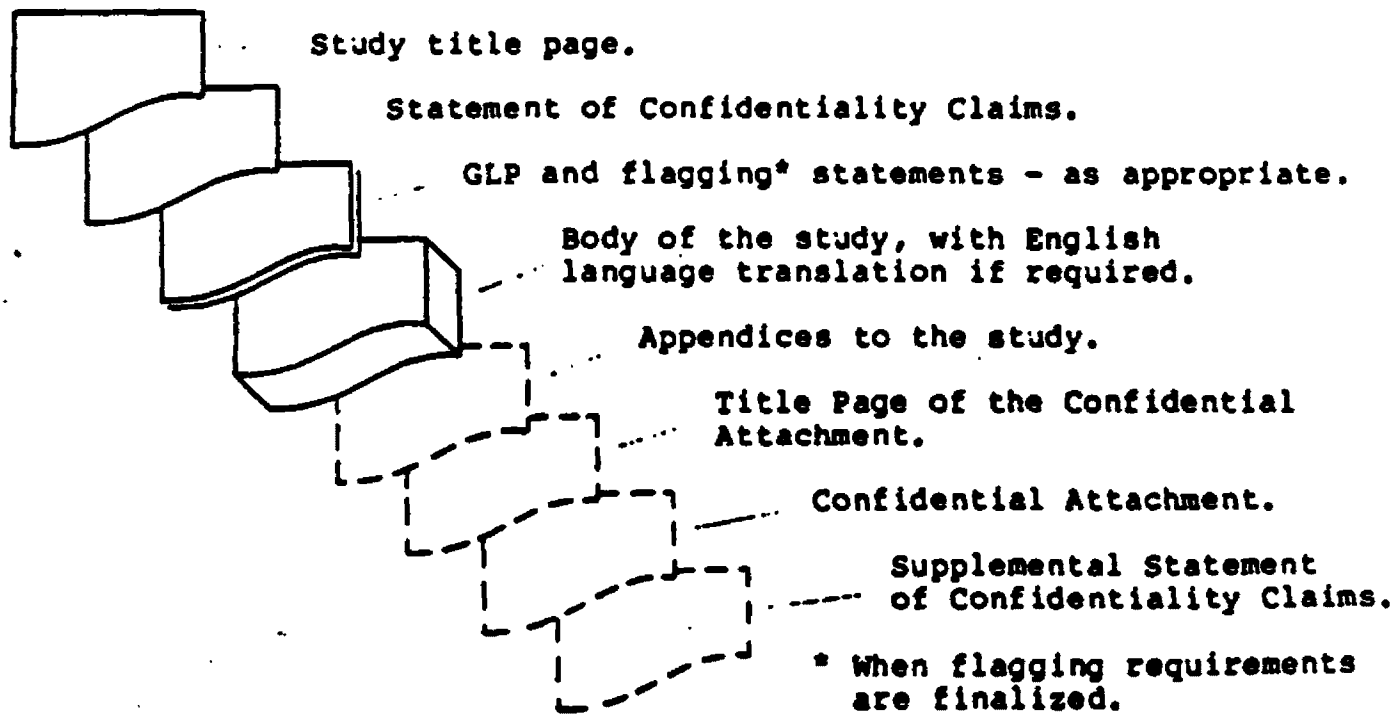
Submitter _____

ATTACHMENT 7.

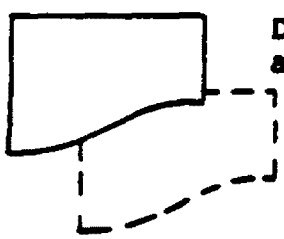
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



EPA

TS-767
United States
Environmental Protection
Agency
Washington, DC 20460

Official Business
Penalty for Private Use
$300

ATTACHMENT D

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

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 $\geq$ 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 $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3)

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.

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 $\geq$ 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

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.

1. Number of representative samples analyzed for all active ingredients and all impurities 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/100 ml (other units like ppm acceptable if sparingly soluble)

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

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

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

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

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig
81-7	Acute Neurotoxicity in the Hen

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc)
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

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, end-use product, 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 and for at least 14 days.
7. Summarization of body weights
8. Summarization of gross necropsy
9. 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._____ Identify material tested (technical, end-use product, etc)

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.
13._____ Individual body weights.
14._____ 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

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, 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 and for at least 14 days or until all animals appear normal (whichever is longer).
12. Summarization of body weights
13. Summarization of gross necropsy
14. 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.____ Identify material tested (technical, end-use product, etc)
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 category 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.
13.____ Individual body weights.
14.____ Gross necropsy on all animals.

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, 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 and for at least 14 days.
12. Summarization of body weights
13. Summarization of gross necropsy
14. 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.____ Identify material tested (technical, end-use product, etc)
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 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

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, etc.
2. State if 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 daily observations afterwards, until eyes are normal or for 21 days
10. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc)
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 hours prior to dosing
7._____ Application site approximately 6 cm.
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 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

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, 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 day of dosing and individual daily observations thereafter
12. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

dose your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc)
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

4.____ Complete description of test
5.*___ Reference for test.
6.____ Test followed essentially as described in reference document.
7.____ Positive control included (may provide historical data conducted within the last 6 months)

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

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, end-use product, 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 is determined.
7.____ Dose tested equal to an acute oral LD 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 sin 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 E

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

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

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 3051 (Coco alkyl)amine salts

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
001100	HULS AMERICA, INC.		BOX 365	PISCATAWAY NJ	08855
004313	CARROLL COMPANY		2900 W. KINGSLEY RD.	GARLAND TX	75041

ATTACHMENT F

COST SHARE AND DATA COMPENSATION FORMS

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

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)	

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

Please fill in blanks below.

Company Name	Company Number

Chemical Name	EPA Chemical Number

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	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number		Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit /rat/g.pig				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto 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.

Typed Name and Title	Signature	Date