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Office of Prevention, Pesticides
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Reregistration Eligibility Document (RED)

540/RS-93-235

Sodium Hydroxide

REREGISTRATION ELIGIBILITY DOCUMENT
SODIUM HYDROXIDE

LIST D

CASE 4065

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

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TABLE OF CONTENTS

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l or ppm.
LD_{50}	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). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDlo	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

NPDES	National Pollutant Discharge Elimination System.
NOEL	No Observed Effect Level. Dose level not associated with toxic effects.
OPP	Office of Pesticide Programs
ppm	Parts Per Million
TD	Toxic Dose. The dose at which a substance produces a toxic effect
ug	Micro-grams

EXECUTIVE SUMMARY

This Reregistration Eligibility Document (RED) addresses pesticide uses of sodium hydroxide. Products containing sodium hydroxide are currently registered as herbicides, fungicides, disinfectants, sanitizers and microbicides/microbiostats (for control of slime-forming bacteria, fungi and algae). Registered use sites include drinking water systems, water well casings, food processing plant premises/equipment, food handling areas (in eating establishments), commercial/institutional/industrial premises, floors and equipment, hospitals/medical institutional premises and sewage systems. All products containing sodium hydroxide as an active ingredient and registered for these uses are eligible for reregistration.

The U.S. Environmental Protection Agency (EPA) has conducted a review of the scientific data bases and other relevant information supporting the reregistration of sodium hydroxide. All applicable toxicology, human exposure, and ecological and environmental effect data requirements have been waived for this active ingredient. The information and data available to the Agency support the conclusion that the currently registered uses of sodium hydroxide will not result in unreasonable adverse effects to human health and the environment.

Accordingly, the Agency has determined that all products containing sodium hydroxide as the active ingredient, are eligible for reregistration and will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, the Agency 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 the revised labels, the Agency will determine whether the conditions of FIFRA 3(c)(5) have been met, that is, whether product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met the Agency will reregister the product. Any end-use products containing sodium hydroxide in combination with other active ingredients will not be reregistered until REDs are issued for all active ingredients contained in that product.

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 the 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 sodium hydroxide. The document consists of six sections. Section I is the introduction. Section II describes sodium hydroxide, 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 sodium hydroxide. Section V covers actions required by registrants of manufacturing-use and end-use products. Section VI contains the appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

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[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. Identification of Active Ingredient

1. **Chemical Name:** Sodium Hydroxide

2. **CAS Number:** 1310-73-2

3. **Office of Pesticide Programs Chemical Code Number:** 076503

4. **Empirical Formula:** NaOH

B. Use Profile

1. **Type of Pesticide:** Herbicide; fungicide; disinfectant; fungicide/fungistat; sanitizer; microbicide/microbistat (slime-forming bacteria, fungi, and algae).

2. **Pests Controlled:** tree roots, fungi, bacteria (unspecified), and slime-forming bacteria, fungi, and algae.

Use Sites	Types of Treatment	Equipment	Timing	Rate of Application
Indoor Food: Human Drinking Water Systems (water well casing); Food Processing Plant Premises (Non-food contact); Food Processing Plant Equipment (Food contact); Eating Establishments Food Handling Areas (Food and Non-food contact).	ground:(except water well casing): mopping, scrubbing, sponge-on, spraying. Well casing: water related surface treatment.	Mop, sponge, sprayer, cloth.(except water well casing). Well casing: water well casing.	When needed, or not on label.	Disinfectant: 164 ppm AI by vol. Sanitizer: 66 ppm AI by vol. (Except water well casing): Well casing: 20,983 ppm AI by wt.
Indoor Non-food: Commercial/ Institutional/Industrial Premises/ Equipment (Indoor).	ground; mopping, scrubbing, sponge-on, spraying.	Mop, sponge, sprayer, cloth.	When needed or not on label.	Disinfectant: 164 ppm AI by vol. Sanitizer: 66 ppm AI by vol.
Indoor Non-food: Commercial/Institutional/I ndustrial Floors (Antimicrobials only).	ground; mopping, scrubbing, sponge-on, spraying.	Mop, sponge, sprayer, cloth.	When needed or not on label.	Disinfectant: 164 ppm AI by vol. Sanitizer: 66 ppm AI by vol.
Indoor Medical: Hospitals/Medical Institutions premises (Human/Veterinary); Hospitals/Medical Institutions Non-conductive Floors.	ground; mopping, scrubbing, sponge-on, spraying.	Mop, sponge, sprayer, cloth.	When needed or not on label.	Disinfectant: 164 ppm AI by vol. Sanitizer: 66 ppm AI by vol.
Aquatic Non-food Industrial/Residential: Sewage Systems.	sewer treatment.	Applied to sewer through toilet bowl using pail, and not on label.	When needed or not on label.	From 0.4284 lb AI/1 linear ft to 425 lb AI/1 linear ft.

3. Formulation Types Registered

a. Type: End Use.

b. Forms: Soluble Concentrate/Liquid, Crystalline, Soluble Concentrate/Solid, Form not identified/solid.

4. Use Practices and limitations:

Do not discharge effluent containing this pesticide into sewer systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or public waters unless specifically identified and addressed in a NPDES permit. For Food Processing Plant Premises/Equipment and Eating Establishment sites: potable water rinse (non-residual claim).

C. Regulatory History

Sodium hydroxide-containing products were initially registered in 1951. The seven currently registered products are used as herbicides, fungicides, disinfectants, sanitizers, microbicide/microbiostats. The Food and Drug Administration, in 21 CFR 184.1763, lists sodium hydroxide as a substance generally recognized as safe (GRAS) for use in food. The listing includes uses as a pH control agent and as a processing aid, with no limitations other than current good manufacturing practice.

Under a memorandum of understanding issued on December 22, 1971, (36 FR 24234), FDA and the Agency defined responsibilities in the regulation of food-contact sanitizing solutions. FDA approves, under food additive regulations, the use of sanitizers on food-contact surfaces. The Agency defers to FDA for dietary risk assessments. This approval includes the toxicological and dietary residue assessments. The Agency focuses on product chemistry, efficacy and applicator risk assessments. Sodium hydroxide containing products registered as sanitizers for food-contact surfaces fall under this agreement. Therefore, for this reregistration assessment of sodium hydroxide, the Agency has not conducted a risk assessment associated with the food-contact surface sanitizer uses. Rather, the Agency defers to FDA's assessment and clearance.

III. SCIENCE ASSESSMENT OF SODIUM HYDROXIDE

The Agency has reviewed the scientific data base for sodium hydroxide. Information considered is primarily from published literature. These are cited in Appendix C.

A. Chemistry Assessment

1. Physical Properties of Sodium Hydroxide

Sodium Hydroxide is a white, crystalline, brittle solid. For laboratory purposes, it is ordinarily sold in the form of sticks, pellets or white flakes. It is often called caustic soda. As this name indicates, it is a corrosive substance and has a strong disintegrating action upon both animal and vegetable tissues. It is extremely soluble in water and a great deal of heat is liberated during solution. When exposed to the air, it absorbs both moisture and carbon dioxide and is changed into sodium carbonate. Its solution has a soapy feel and a strong cleansing action.

Solubilization results in immediate dissociation into sodium and hydroxide ions to the following equation: $NaOH = Na^{+} + OH^{-}$. The pH values of unbuffered water containing sodium hydroxide from 0.1 to 10,000 parts per million (ppm) range from 8.4 to 13.4, respectively.

2. Manufacturing Methods and Non-pesticidal Industrial Uses

The primary source of sodium hydroxide is by the electrolysis of sodium chloride solutions, which also yields chlorine as a secondary product during manufacturing. Also sodium hydroxide may be produced by reacting calcium hydroxide with sodium carbonate. [1, 4]

Sodium hydroxide is used in many chemical industries. Its major industrial uses are in the rayon, film and chemical industries. It is also used by soap manufacturers, petroleum refineries, textile producers and pulp and paper manufacturers. [1]

B. Human Health Assessment

The toxicological data base on sodium hydroxide is adequate and will support reregistration. Sodium hydroxide is a widely-used chemical and the toxicity has been known generally for some time.

1. Acute Toxicity

TABLE OF ACUTE TOXICITY DATA FOR SODIUM HYDROXIDE:		
TEST RESULT	(mg/kg)	TOXICITY CATEGORY
Acute Oral Lethal Dose-Rabbit	500	II
Eye Irritation	Corrosive	I
Skin Irritation	Corrosive	I
Acute Dermal Toxicity Acute Inhalation Toxicity	Corrosive	

Sodium hydroxide is corrosive and irritating to skin, eyes and mucous membranes [1, 2]. The oral lethal dose for rabbits is reported to be 500 mg/kg [1, 3]. Corrosion of gastric mucosa and perforation of the stomach wall were found in rabbits given 5 to 12 g/kg of sodium hydroxide in milk [3].

A solution of 5 percent sodium hydroxide in water produced severe necrosis on rabbit skin when applied for 4 hours [2]. The application of 50 ug of sodium hydroxide to rabbit eyes for 24 hours caused severe irritation [1].

2. Subchronic Toxicity

When rats were exposed to an aerosol of 40 percent sodium hydroxide for 30 minutes twice a week, two of 10 rats died after 3 weeks, with bronchial ulceration and lung effects [2].

3. Metabolism

Free alkalis, such as sodium hydroxide, are converted to neutral salts by the acids in the stomach [3].

4. Chronic, Carcinogenicity Studies

In an experiment in painting sodium hydroxide on the skin of mice, carcinogenicity was not found [3]. Mice given sodium hydroxide by mouth for 10 months, equivalent to 200 mg/kg, did not show carcinogenicity in the digestive system [3]. No adverse effects were found in rats receiving 1 mg/kg by gavage three times a week for 93 days [3].

5. Mutagenicity

Tests with E. coli strain Sd-4 did not indicate mutagenic activity with sodium hydroxide [3].

6. Other Toxicity Information

From observations of accidental and intentional human poisoning cases, it has been estimated that the fatal dose of sodium hydroxide is less than 10 g [3]. In non-fatal cases of ingestion, sodium hydroxide was found to cause severe esophageal stricture [2]. Skin from human volunteers, where 1 N sodium hydroxide had been applied for 15-180 minutes, showed progressive changes from cell dissolution in the horny layer, through edema, to total destruction of the epidermis [2].

7. Dietary Exposure

There are no direct pesticidal food uses for sodium hydroxide. However, products containing sodium hydroxide are registered for use on food contact surfaces and well-head casings. These applications have been assessed by FDA memorandum of understanding discussed above in section II. C., Regulatory History.

8. Occupational and Residential Exposure

Sodium hydroxide is formulated in soluble concentrates and dry flowables containing 1.05-98.5% sodium hydroxide combined with one or more of the following active ingredients: copper sulfate, sodium chloride, sodium metasilicate, sodium carbonate, trisodium phosphate, sodium dodecylbenzenesulfonate, sodium dichloro-s-triazinetrione, 2,6-dichlorobenzonitrile, alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chloride and alkyl (60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}) dimethyl benzyl ammonium chloride. These mixtures are applied undiluted, or diluted with water by pouring into drains or spraying water dilutions on surface sites.

9. Risk Assessment

There is no reason to expect that all current usage of sodium hydroxide as a pesticide, with appropriate precautions, will constitute any unreasonable hazard from ordinary exposure.

Sodium hydroxide is corrosive and irritating to skin, eyes, and mucous membranes and has a moderate acute oral toxicity. Based on the application methods and formulation types for products containing sodium hydroxide, the potential for significant eye and dermal exposure to mixers, loaders, and applicators in commercial and institutional settings exists. However, providing the products are used in accordance with appropriate label precautions for eye and dermal protection, the potential worker exposure should be minimal. For the food contact surface uses, the Agency defers to FDA and their acceptance of risks associated with these uses.

10. Precautionary Labeling

Based on the application methods and formulation types, the potential for significant eye and dermal exposure to mixers, loaders, and applicators in commercial and institutional settings exists. Appropriate label precautions for eye and skin protection are required since sodium hydroxide is corrosive. Refer to Section V. D., Labeling Requirements for End-Use Products below for more details.

C. Environmental Fate and Ecological Effects Assessment

There are no outstanding environmental fate data requirements for the uses since there is sufficient information in the public literature on the fate of sodium hydroxide in the environment. See Section III.A., Chemistry Assessment, above for more details.

The use of sodium hydroxide in sewage systems is also regulated by state regulatory agencies, through a National Pollutant Discharge Elimination System (NPDES) permit for environmental discharges, the Agency did not conduct a risk assessment for this current use. Compliance with the National pollutant Discharge Elimination System (NPDES) permit is required for sewer treatment. In many instances, the ultimate destination of the effluent from the sewer drain is the local sewage treatment plant. In the unlikely event that the waste in the sewer line would have a higher pH due to the addition of sodium hydroxide, the sewage treatment plant would be required to adjust the pH of the total effluent to be in compliance with a NPDES permit. The Agency has determined that bioassays on fish and aquatic invertebrates conducted under standardized test conditions, including buffered water, would yield LC_{50}/EC_{50} values greater than 1 ppm. Therefore, no environmental precautions pertaining to aquatic toxicity statement would be required. No further data are needed for product labeling for these uses.

The risk for using products containing sodium hydroxide on well-head casings to control slime would occur at the time that the treated water is discharged. In addition to the varied buffering capacity of different waters, the initial pH in the well water is unpredictable. However, use instructions require a minimum holding time period of 24 hours, during which the pH may decrease. In addition, exposure to terrestrial organisms such as birds and mammals to the discharged water would be expected to be small and of short duration.

2. Precautionary Labeling

a. For manufacturing-use products and end use products for controlling roots in sanitary sewer lines, the Agency requires a label statement about these products' toxicity to wildlife and the requirement for a NPDES permit prior to discharge. [Residential use is exempt from this requirement.] Refer to Section V. D., Labeling Requirements for End-Use Products, below for specific labeling.

b. For end-use products for use on well-head casings the Agency requires label statements concerning wildlife toxicity and a prohibition against contamination of water by disposal of equipment, wash-water, or rinsate. Refer to Section V. D., Labelng Requirements for End-Use Products, below for specific labeling.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR SODIUM HYDROXIDE

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 sodium hydroxide are eligible for reregistration. The Agency has waived submission of all generic data requirements except basic product identity and chemistry. The Agency has completed its review of all available information, and has determined that the data are sufficient to support reregistration of products containing sodium hydroxide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium hydroxide and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess registered uses of sodium hydroxide and to determine that these uses can be used without resulting in unreasonable adverse effects to humans and the environment. While the Agency lacks certain chemistry data to support the purity of each technical source of sodium hydroxide, it has no reason to suspect any source contains impurity of concern. Nevertheless, the Agency is requiring such data to confirm this. Refer to Section VI., B., below for these data requirements. The Agency therefore finds that products containing sodium hydroxide as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

Although the Agency has found that certain products containing sodium hydroxide 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 the registration of products containing sodium hydroxide, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

V. ACTIONS REQUIRED BY REGISTRANTS OF MANUFACTURING-USE USE PRODUCTS

A. Determination of Eligibility

1. Based on the Agency's reviews of the generic data base for the active ingredient sodium hydroxide, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data and revised product labels, 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.

B. Additional Generic Data Requirements

The generic data base supporting the reregistration of products containing sodium hydroxide has been reviewed and determined to be sufficiently complete to allow the Agency to reach its decision of reregistration eligibility. The following generic data for sodium hydroxide have not been submitted and are required to confirm the manufacturing process(es) and impurities of each technical grade source used in registered products. These data are due to the Agency within eight months of [start clock same as product specific data requirements]. The Agency will include its review of these data in its decision whether to reregister individual products.

- All available technical specifications, data sheets and other documents by which the manufacturer, producer or supplier describes the composition information.

- A description of the manufacturing process(es) for all sources of sodium hydroxide used in all registered products.

- A discussion of any impurities present for all technical sources of sodium hydroxide.

C. Product Specific Data Requirements

The Agency is waiving all the acute toxicity data requirements for the end-use products, because of the corrosive characteristics of the chemical, and shall rely on the toxicity categories established for the active ingredient. To characterize the product chemistry and efficacy of individual products, the Agency is requiring the product-specific data requirements stated in Attachment F.

D. Labeling Requirements for End-Use Products

The labeling of all products must comply with the Agency's current regulations and requirements as specified in 40 CFR 156.10. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling. Additionally the following precautionary statements are required.

1. Precautionary Labeling

For manufacturing-use and end-use products for controlling roots in sanitary sewer lines:

a. This pesticide is toxic to wildlife. 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 a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional office of the U. S. Environmental Protection Agency. [Residential use is exempt from this requirement.]

b. For end-use products for use on well-head casings the Agency requires label statements concerning wildlife toxicity and prohibition against contamination of water by disposal of equipment, wash water, or rinsate.

c. Additionally for all end-use products:
The Agency is requiring the following label statement on end-use products to mitigate the potential for irreversible eye tissue damage: "When using this product, wear eye goggles or safety glasses". The Agency may impose additional product specific pre-cautions and requirements for eye and dermal protection when product-specific data has been submitted and reviewed and determined to be acceptable.

VI. APPENDICES

APPENDIX A - Use Patterns Subject to Reregistration

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appo.	Max. # Appo. @ Max. Rate	Min. Interval Between Appo. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
FOOD/FEED USES										
Food Processing Plant Equipment (Food Contact) Use Groups: Indoor Food										
Equipment treatment, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Equipment treatment, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Equipment treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Equipment treatment, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Food Processing Plant Premises Use Groups: Indoor Food										
Premise treatment, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Premise treatment, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Food Processing Plant Premises Use Groups: Indoor Food										

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Premise treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Premise treatment, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Eating Establishments Food Handling Areas (Food Contact) Use Groups: Indoor Food										
Surface treatment, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Eating Establishments Food Handling Areas (Non-food contact) Use Groups: Indoor Food										
Surface treatment, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Surface treatment, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. Remove, protect food products and packaging materials. Potable water rinse.
Human Drinking Water Systems Use Groups: Indoor Food										
Water Related Surface Treatment, Not on Label, Not on Label	SC/S	NA	20,983 ppm by Wt.	Not spec.	Not spec.	NA	Not spec.	NA	NA	Pump the first water after treatment to waste.
NON-FOOD/NON-FEED USES										
Commercial/Institutional/Industrial Premises/Equipment Use Groups: Indoor Non-Food										
Mop, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Sponge-On, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Commercial/Institutional/Industrial Premises/Equipment Use Groups: Indoor Non-Food										
Spray, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Surface treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Scrub, Not on Label, Not on Label	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Hospitals/Medical Institutions Premises (Human/Veterinary) Use Groups: Indoor Medical										
Mop, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Sponge-On, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Spray, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Scrub treatment, Not on Label, Not on Label	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Premise treatment, Not on Label, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Hospitals/Medical Institutions Non-conductive Floors Use Groups: Indoor Medical										
Mop, Not on Label, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Sponge-On, Not on Label, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Spray, Not on Label, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Scrub treatment, Not on Label, Not on Label	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean.
Commercial/Institutional/Industrial Floors (Antimicrobials Only) Use Groups: Indoor Non-Food										
Mop, When Needed, Mop	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. (Label dose for removing heavy soil/buildup is 656 ppm AI.)
Sponge-On, When Needed, Sponge	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. (Label dose for removing heavy soil/buildup is 656 ppm AI.)
Spray, When Needed, Sprayer	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. (Label dose for removing heavy soil/buildup is 656 ppm AI.)
Scrub, When Needed, Cloth	SC/L	66 ppm by Vol. (sanitize)	164 ppm by Vol. (disinfect)	Not spec.	Not spec.	NA	Not spec.	NA	NA	Preclean. (Label dose for removing heavy soil/buildup is 656 ppm AI.)

APPENDIX A - Case 4065, [Mineral bases, strong] Chemical 075603 [Sodium Hydroxide]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Sewage Systems Use Groups: Aquatic Non-Food Industrial										
Sewer Treatment, When Needed, Not on Label	SC/L	NA	107 lb AI per 1K ft	Not spec.	Not spec.	NA	Not spec.	NA	NA	
	FNI/S	NA	78.4 lb AI per linear/ft	Not spec.	Not spec.	NA	Not spec.	NA	NA	
	SC/S	NA	Dose cannot be calculated	Not Spec	Not spec.	NA	Not spec.	NA	NA	
Sewer Treatment, When Needed, Toilet Bowl	Cr	NA	0.6 lb AI per ft	Not spec.	Not spec.	NA	Not spec.	NA	NA	NPDES permit required. Do not discharge effluent into sewer systems without previously notifying sewage treatment plant authority.
	SC/L	NA	Dose cannot be calculated	Not spec.	Not spec.	NA	Not spec.	NA	NA	
	FNI/S	NA	Dose cannot be calculated	Not spec.	Not spec.	NA	Not spec.	NA	NA	

Abbreviations used

Header: Max = Maximum; Min = Minimum; Appls = Applications.
Form: SC/L = Soluble Concentrate/Liquid; SC/S = Soluble Concentrate/Solid; FNI/S = Form Not Identified/Solid; Cr = Crystalline.
Rate: AI = Active Ingredient; A = Acre; ppm = parts per million; Vol. = Volume.

Other: Not spec. = Not specified; NA = Not Applicable.

APPENDIX B

Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for sodium hydroxide covered by this Reregistration Eligibility document. It contains generic data requirements that apply to sodium hydroxide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in 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 se in the Pesticide assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this colum 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 appendix for a complete citation of the study.

SODIUM HYDROXIDE

		USE SITES	BIBLIOGRAPHIC CITATION
PRODUCT CHEMISTRY			
61-1	Chemical Identity	F,L,M,N	DATA GAP
61-2	Beginning Materials and Manufacturing Process	F,L,M,N	DATA GAP
61-3	Formulation of Impurities	F,L,M,N	DATA GAP
62-1	Preliminary Analysis	F,L,M,N	WAIVED
62-3	Analytical Methods	F,L,M,N	WAIVED
63-2	Color	F,L,M,N	WAIVED
63-3	Physical State	F,L,M,N	WAIVED
63-4	Odor	F,L,M,N	WAIVED
63-5	Melting Point	F,L,M,N	WAIVED
63-7	Density	F,L,M,N	WAIVED
63-8	Solubility	F,L,M,N	WAIVED
63-10	Dissociation Constant	F,L,M,N	WAIVED
63-11	Octanol/Water Partition Coefficient	F,L,M,N	WAIVED
63-12	pH	F,L,M,N	WAIVED

ENVIRONMENTAL FATE

EPA waived 40 CFR part 158 generic data requirements for reasons discussed in section III.

TOXICOLOGY

EPA waived 40 CFR part 158 generic data requirements for reasons discussed in section III.

ECOLOGICAL EFFECTS

EPA waived 40 CFR part 158 generic data requirements for reasons discussed in section III.

RESIDUE CHEMISTRY

EPA waived 40 CFR part 158 generic data requirements for reasons discussed in section III.

HUMAN EXPOSURE

EPA waived 40 CFR part 158 generic data requirements for reasons discussed in section III.

Citations listed in the bibliography (Appendix C) were used to support these decisions.

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Sodium Hydroxide

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

2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted 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 whenever a specific reference is required. It is not related to the six-digit "Accession Number" that 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 identifying number is also to be used whenever specific reference is needed.

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

   a. Author. Whenever the author could confidently be identified, 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 the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained 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 the 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:

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. 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", which stands 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.

BIBLIOGRAPHY

(1) Sax, N. I., and Lewis, R. J. SR, 1989. Dangerous Properties of Industrial Materials, 7th Edition. Van Nostrand Reinhold, New York.

(2) Clayton, G. D., and Clayton, F. E., eds., 1982. Patty's Industrial Hygiene and Toxicology, 3rd. Revised Edition. Wiley Interscience, NY.

(3) FASEB, 1976. "Evaluation of the Health Aspects of Sodium Hydroxide and Potassium Hydroxide as Food Ingredients." SCOGS-85.

(4) Windholz, M., Budavari, S., Blumetti, R., and Otterbein, E., Eds., 1983. "The Merck Index." Merck & Co., Inc.

APPENDIX D
List of Available Related Documents and 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).

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

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

List of Available Related Documents

The following is a list of available documents related to sodium hydroxide. Its purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for sodium hydroxide and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Sodium hydroxide RED Fact Sheet

4. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E

Pesticide Reregistration Handbook

APPENDIX F

Generic Data Call-In

Attachment A

Chemical Status Sheet

SODIUM HYDROXIDE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing sodium hydroxide.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of sodium hydroxide. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this Sodium Hydroxide Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for sodium hydroxide are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on sodium hydroxide are needed. These data are needed to fully complete the reregistration of all products containing sodium hydroxide.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Richard Gebken at (703) 308-8591.

All responses to this Notice for the generic data requirements should be submitted to:

Richard J. Gebken, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: SODIUM HYDROXIDE

Attachment B

Generic DCI 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
000500 BOYER CORPORATION BOX 10 LA GRANGE IL, 60525	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

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 an 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."
500-22					

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
007742 KING OF ALL MANUFACTURING INC. 2601 DAVISON RD FLINT MI, 48506	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

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 an 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."
7742-8					

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
008132 ROOTO CORP 3505 WEST GRAND RIVER HOWELL MI, 48843	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

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 an 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."
8132-3					

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
009429 COTEY CHEMICAL COMPANY 1939 AVENUE H LUBBOCK TX, 79404	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

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 an 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."
9429-2					

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
009902 IRON OUT, INC. 1515 DIVIDEND RD FORT WAYNE IN, 46808	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

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 an 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."
9902-1					

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 010700
GALAXY CHEMICAL COMPANY INC.
1620 SOUTH CANAL STREET
CHICAGO IL, 60616

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

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 an 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."
10700-2					

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

(who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is a end use product for which you agree to supply product-specific data. Attach the Requirements Status and Reqistrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

Attachment C

Product Specific Requirement Status and Registrants' Response Forms (Form B) plus Instructions and PR Notice 86-5

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

JUL 29 1986

PR NOTICE 86-5 OFFICE OF

- INDEX -

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

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 tne typed name and title of the official who signed it.

5.5 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 _____

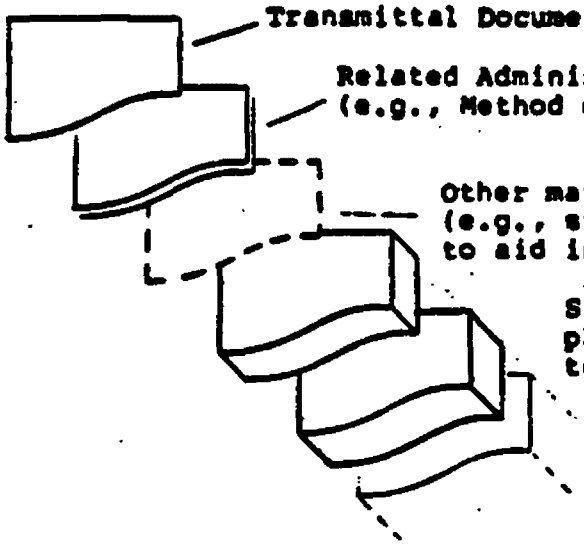
Example 3.

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.

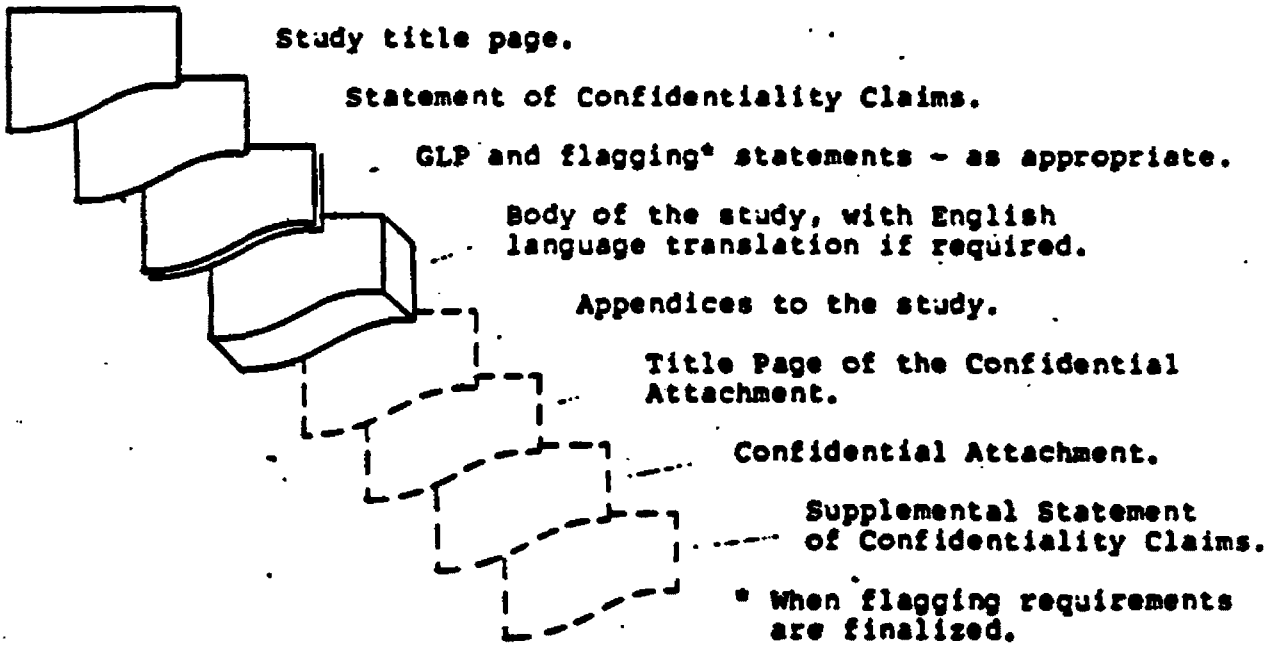
Submitter _____

ATTACHMENT 7.

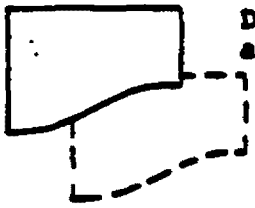
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



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 000500
BOYER CORPORATION
BOX 10
LA GRANGE IL 60525

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number		5. Study Title	DATA ORDER	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	*	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
61-1	Information on the composition of the Technical Grade Active Ingredient (TGAI) must be furnished according to the requirements of 40 CFR 158.165. A Confidential Statement of formula (CSF) and label for sodium hydroxide technical must also be provided to the Agency.
61-2(a)	The identity of the materials used to produce the technical grade active ingredient, the relative order in which they are added, the description of the manufacturing process (including the description of the conditions controlled in each step that would affect the composition of the product an the purification methods to assure consistent composition of the product) should be described. as required by 40 CFR 158.160.
61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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 007742
KING OF ALL MANUFACTURING INC.
2601 DAVISON RD
FLINT MI 48506

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

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
61-1 *	Chemical Identity					all	TGAI	12 mos.	
61-2(a) *	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b) *	Discussion of Impurities					all	TGAI	12 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

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*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
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61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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 ,008132
ROOTO CORP
3505 WEST GRAND RIVER
HOWELL MI 48843

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number		5. Study Title	DCI	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mfg. proc					all	TGAI	12 mos.	
61-2(b)	*	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
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61-2(a)	The identity of the materials used to produce the technical grade active ingredient, the relative order in which they are added, the description of the manufacturing process (including the description of the conditions controlled in each step that would affect the composition of the product an the purification methods to assure consistent composition of the product) should be described. as required by 40 CFR 158.160.
61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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 009429
COTEY CHEMICAL COMPANY
1939 AVENUE H
LUBBOCK TX 79404

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

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
61-1 *	Chemical Identity					all	TGAI	12 mos.	
61-2(a) *	Begin. mat. & mfg. proc					all	TGAI	12 mos.	
61-2(b) *	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
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61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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
009902 IRON OUT, INC. 1515 DIVIDEND RD FORT WAYNE IN 46808	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

4. Guideline Requirement Number		5. Study Title	DATA	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	12 MOS.	
61-2(a)	*	Begin. mat. & mfg. proc					all	TGAI	12 MOS.	
61-2(b)	*	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
61-1	Information on the composition of the Technical Grade Active Ingredient (TGAI) must be furnished according to the requirements of 40 CFR 158.165. A Confidential Statement of formula (CSF) and label for sodium hydroxide technical must also be provided to the Agency.
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61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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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
010700 GALAXY CHEMICAL COMPANY INC. 1620 SOUTH CANAL STREET CHICAGO IL 60616	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	GENERIC

4. Guideline Requirement Number		5. Study Title	Data Source	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b)	*	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
61-1	Information on the composition of the Technical Grade Active Ingredient (TGAI) must be furnished according to the requirements of 40 CFR 158.165. A Confidential Statement of formula (CSF) and label for sodium hydroxide technical must also be provided to the Agency.
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61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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 011364
KENNEDY CONSULTANTS
AGENT FOR: ANGUS CHEMICAL CORP
9101 CHERRY LANE SUITE 113
LAUREL MD 20781

2. Case # and Name
4065 Mineral bases, strong
Chemical # and Name 075603
Sodium hydroxide

3. Date and Type of DCI
GENERIC

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
61-1 *	Chemical Identity					all	TGAI	12 mos.	
61-2(a) *	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
61-2(b) *	Discussion of Impurities					all	TGAI	12 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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
61-1	Information on the composition of the Technical Grade Active Ingredient (TGAI) must be furnished according to the requirements of 40 CFR 158.165. A Confidential Statement of formula (CSF) and label for sodium hydroxide technical must also be provided to the Agency.
61-2(a)	The identity of the materials used to produce the technical grade active ingredient, the relative order in which they are added, the description of the manufacturing process (including the description of the conditions controlled in each step that would affect the composition of the product an the purification methods to assure consistent composition of the product) should be described. as required by 40 CFR 158.160.
61-2(b)	The formation and identification of all impurities must be identified as required by 40 CFR 158.167, and 40 CFR 158.155 (c), (d) and (f).

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly **(Cost Sharing)**. I am submitting a **copy of this agreement.** I understand that this option is available **only** for acute toxicity or certain efficacy data **and only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

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

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

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

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed **"Certification With Respect To Data Compensation Requirements" form.**

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my

request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

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

Attachment D

List of all Registrant(s) sent this DCI

List of All Registrants Sent This Data Call-In Notice

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

Company Number	Company Name	Additional Name	Address	City & State	Zip
000500	BOYER CORPORATION		BOX 10	LA GRANGE IL	60525
007742	KING OF ALL MANUFACTURING INC.		2601 DAVISON RD	FLINT MI	48506
008132	ROOTO CORP		3505 WEST GRAND RIVER	HOWELL MI	48843
009429	COTEY CHEMICAL COMPANY		1939 AVENUE H	LUBBOCK TX	79404
009902	IRON OUT, INC.		1515 DIVIDEND RD	FORT WAYNE IN	46808
010700	GALAXY CHEMICAL COMPANY INC.		1620 SOUTH CANAL STREET	CHICAGO IL	60616
011364	KENNEDY CONSULTANTS	AGENT FOR: ANGUS CHEMICAL CORP	9101 CHERRY LANE_SUITE 113	LAUREL MD	20781

Attachment E

Cost Share/Data Compensation Forms

APPENDIX G

Product Specific Data Call-In

Attachment A

Chemical Status Sheet

SODIUM HYDROXIDE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 sodium hydroxide Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

The Agency has concluded that product specific data are needed for sodium hydroxide. 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 the Registration Division Product Manager 23 (PM 23) who is assigned to the product, Joanne Miller at (703) 305-7830. All responses to this Notice should be submitted to:

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

RE: Sodium Hydroxide

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Richard J. Gebken at (703) 308-8591. All responses to this Notice should be submitted to:

Chemical Review Manager Richard J. Gebken
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: Sodium Hydroxide

Attachment B

Product Specific DCI 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
000500 BOYER CORPORATION BOX 10 LA GRANGE IL, 60525	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
500-22					

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
007742 KING OF ALL MANUFACTURING INC. 2601 DAVISON RD FLINT MI, 48506	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
7742-8					

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
008132 ROOTO CORP 3505 WEST GRAND RIVER HOWELL MI, 48843	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
8132-3					

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
009429 COTEY CHEMICAL COMPANY 1939 AVENUE H LUBBOCK TX, 79404	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
9429-2					

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
009902 IRON OUT, INC. 1515 DIVIDEND RD FORT WAYNE IN, 46808	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
9902-1					

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
010700 GALAXY CHEMICAL COMPANY INC. 1620 SOUTH CANAL STREET CHICAGO IL, 60616	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
10700-2					

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
011364 KENNEDY CONSULTANTS AGENT FOR: ANGUS CHEMICAL CORP 9101 CHERRY LANE SUITE 113 LAUREL MD 20781	4065 Mineral bases, strong Chemical # and Name 075603 Sodium hydroxide	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 an 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."
11364-5					

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

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

Attachment C

Requirements Status and Registrants' Response Forms (Form B) plus Instructions

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
BOYER CORPORATION BOX 10 LA GRANGE IL 60525	4065 Mineral bases, strong EPA Reg. No. 500-22	PRODUCT SPECIFIC ID# 500-RD-2309

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

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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
BOYER CORPORATION BOX 10 LA GRANGE IL 60525	4065 Mineral bases, strong EPA Reg. No. 500-22	PRODUCT SPECIFIC ID# 500-RD-2309

4. Guideline Requirement Number	5. Study Title	Data Gap	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
KING OF ALL MANUFACTURING INC. 2601 DAVISON RD FLINT MI 48506	4065 Mineral bases, strong EPA Reg. No. 7742-8	PRODUCT SPECIFIC ID# 7742-RD-2311

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

10. Certification

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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
KING OF ALL MANUFACTURING INC. 2601 DAVISON RD FLINT MI 48506	4065 Mineral bases, strong EPA Reg. No. 7742-8	PRODUCT SPECIFIC ID# 7742-RD-2311

4. Guideline Requirement Number	5. Study Title		Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient	(8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH	(9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

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

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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
ROOTO CORP
3505 WEST GRAND RIVER
HOWELL MI 48843

2. Case # and Name
4065 Mineral bases, strong

EPA Reg. No. 8132-3

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 8132-RD-2312

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

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

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

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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
ROOTO CORP 3505 WEST GRAND RIVER HOWELL MI 48843	4065 Mineral bases, strong EPA Reg. No. 8132-3	PRODUCT SPECIFIC ID# 8132-RD-2312

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition (8) coefficient					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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Washington, D. C. 20460

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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
COTEY CHEMICAL COMPANY 1939 AVENUE H LUBBOCK TX 79404	4065 Mineral bases, strong EPA Reg. No. 9429-2	PRODUCT SPECIFIC ID# 9429-RD-2313

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

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

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United States Environmental Protection Agency
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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
COTEY CHEMICAL COMPANY 1939 AVENUE H LUBBOCK TX 79404	4065 Mineral bases, strong EPA Reg. No. 9429-2	PRODUCT SPECIFIC ID# 9429-RD-2313

4. Guideline Requirement Number	5. Study Title	Reserved	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
IRON OUT, INC. 1515 DIVIDEND RD FORT WAYNE IN 46808	4065 Mineral bases, strong EPA Reg. No. 9902-1	PRODUCT SPECIFIC ID# 9902-RD-2314

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

10. Certification

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Signature and Title of Company's Authorized Representative_____

11. Date

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Washington, D. C. 20460

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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
IRON OUT, INC. 1515 DIVIDEND RD FORT WAYNE IN 46808	4065 Mineral bases, strong EPA Reg. No. 9902-1	PRODUCT SPECIFIC ID# 9902-RD-2314

4. Guideline Requirement Number	5. Study Title	Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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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
GALAXY CHEMICAL COMPANY INC. 1620 SOUTH CANAL STREET CHICAGO IL 60616	4065 Mineral bases, strong EPA Reg. No. 10700-2	PRODUCT SPECIFIC ID# 10700-RD-2315

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

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

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13. Phone Number

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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
GALAXY CHEMICAL COMPANY INC. 1620 SOUTH CANAL STREET CHICAGO IL 60616	4065 Mineral bases, strong EPA Reg. No. 10700-2	PRODUCT SPECIFIC ID# 10700-RD-2315

4. Guideline Requirement Number	5. Study Title	Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
KENNEDY CONSULTANTS AGENT FOR: ANGUS CHEMICAL CORP 9101 CHERRY LANE SUITE 113 LAUREL MD 20781	4065 Mineral bases, strong EPA Reg. No. 11364-5	PRODUCT SPECIFIC ID# 11364-RD-2316

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

10. Certification

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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
KENNEDY CONSULTANTS
AGENT FOR: ANGUS CHEMICAL CORP
9101 CHERRY LANE SUITE 113
LAUREL MD 20781

2. Case # and Name
4065 Mineral bases, strong

EPA Reg. No. 11364-5

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 11364-RD-2316

4. Guideline Requirement Number	5. Study Title	Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

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

Date

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

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

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

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

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my

request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

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

Attachment D

List of all Registrant(s) sent this DCI

List of All Registrants Sent This Data Call-In Notice

Case # and Name
4065 Mineral bases, strong
Chemical # and Name
075603 Sodium hydroxide

Company Number	Company Name	Additional Name	Address	City & State	Zip
000500	BOYER CORPORATION		BOX 10	LA GRANGE IL	60525
007742	KING OF ALL MANUFACTURING INC.		2601 DAVISON RD	FLINT MI	48506
008132	ROOTO CORP		3505 WEST GRAND RIVER	HOWELL MI	48843
009429	COTEY CHEMICAL COMPANY		1939 AVENUE H	LUBBOCK TX	79404
009902	IRON OUT, INC.		1515 DIVIDEND RD	FORT WAYNE IN	46808
010700	GALAXY CHEMICAL COMPANY INC.		1620 SOUTH CANAL STREET	CHICAGO IL	60616
011364	KENNEDY CONSULTANTS	AGENT FOR: ANGUS CHEMICAL CORP	9101 CHERRY LANE_SUITE 113	LAUREL MD	20781

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

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

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

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

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

Table I. All products containing sodium hydroxide were batched together. It was felt that the high percentage of sodium hydroxide was the major factor in determining the toxicity and

irritation potential of these products, and all these products would have a comparable toxicity and irritation profile.

EPA REG. NO.	% of Sodium Hydroxide & Other Active Ingredients	Formulation Type
500-22	98.50% - Sodium Hydroxide	Granular
7742-8	80.00% - Sodium Hydroxide 20.00% - Sodium Chloride	Granular
8132-3	85.69% - Sodium Hydroxide 0.30% - Copper Sulfate	Granular
9902-1	98.00% - Sodium Hydroxide 2.00% - Copper Sulfate	Granular
9429-2	70.00% - Sodium Hydroxide 15.00% - Sodium Metasilicate	Granular
10700-2	85.00% - Sodium Hydroxide 0.30% - Copper Sulfate	Granular
11364-5	56.00% - Sodium Hydroxide 0.50% - Dichlobenil	Granular

Attachment E

EPA Acceptance Criteria

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

81-3 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.

81-2 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

81-2 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.

81-1 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

81-1 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.

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

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.

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

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.]

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 $\geq$ 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).

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

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.

8. (continued)

____ 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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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 $\leq$ 2 or $\geq$ 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

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.____ 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 F

Cost Share/Data Compensation Forms