US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

SEP 30 1992

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency (the "Agency") has completed its reregistration eligibility decision on the pesticide active ingredient sodium hydroxide.

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient sodium hydroxide. The RED is the Agency's evaluation of the sodium hydroxide data base, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for rereregistration. Also enclosed is the **EPA RED facts** and the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies outstanding product specific data requirements for end-use products and manufacturing-use products. These requirements are listed on the Requirements Status and Registrant's Response Form, which, along with the Data Call-In Response Form listing all of your company's products subject to the RED, is included as an attachment. Instructions for completing both forms are contained in the RED package. All product specific data must be submitted and found acceptable by the Agency before a product can be reregistered.

Generic data requirements usually will have been fulfilled prior to making a reregistration eligibility decision. However, there may be some instances where additional generic data are required. If generic data requirements need to be fulfilled, all registrants must complete the appropriate Data Call-In Response Form and Requirements Status and Registrant's Response Form. These forms are in the appendices to the RED.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generc data for the active ingredient. In addition, in order to

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be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 90 Days of Your Receipt of this Letter

1. For **each product** which is subject to this RED, **you must complete, sign and submit the data call-in (DCI) response forms attached to the RED** [Appendix G, Attachments B and C, has forms for product specific data]. Follow the instructions in Attachments B and C for completing those forms and submit the forms to the appropriate address specified in the Data Call-Ins. **Note that the DCI forms for generic data are to be sent to the Special Review and Reregistration Division (use the mailing distribution code RED-SRRD-4065 for your generic response). The DCI forms for product specific data are to be sent to the Registration Division (use the mailing distribution code RED-RD-PM23 for your product specific response).**

2. **No time extensions will be granted for submitting the 90-day responses.** If the Agency does not receive a response for a product, it may issue a Notice of Intent to Suspend (NOIS) for that product.

3. **Any requests for data waivers or time extensions to the 8-month deadline must be submitted as part of your 90-day response.** Such requests will generally not be considered if submitted later than the 90-day response.

Within 8 Months of the Date of this Letter

1. For **each product**, you must submit a completed **Application for Reregistration** (EPA Form 8570-1), **five copies of the label and labeling** revised as specified by the RED and in accordance with current requirements, **two completed copies of the Confidential Statement of Formula** (CSF) (EPA Form 8570-4), a completed **Certification with Respect to Citation of Data** (EPA

data formatting requirements in P.R. Notice 86-5. Failure to adequately comply with the data requirements specified in this RED may result in the Notice of Intent to Suspend your product.

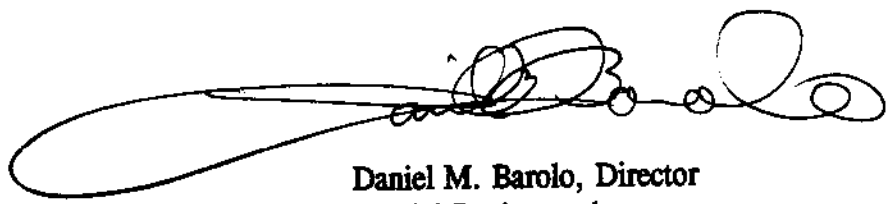
3. The labeling and CSF which you submit for **each** product must **comply with P.R. Notice 91-2** (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the **nominal concentration** rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).

4. Send your Application for Registration to the **Registration Division Product Manager 23 (PM 23) who is assigned to the product, Joanne Miller.** Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is RED-RD-PM23.

Questions on **product specific data requirements and labeling** (for both End-use and Manufacturing-use products) should be directed to the **Registration Division Product Manager 23 Team member** for sodium hydroxide, **Eugene Wilson at (703) 305 - 6103.** Questions on the **generic data requirements** should be directed to **Richard J. Gebken, the Chemical Review Manager** in the **Special Review and Reregistration Division at (703) 308 - 8591.**

The Agency is prepared to meet with any registrants who have questions about responding to the sodium hydroxide RED. **If you wish to meet with the Agency, you must contact Mr. Eugene Wilson within two weeks of your receipt of the RED.** The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,



Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (H-7508W) | EPA-738-F-92-008 September 1992

EPA R.E.D. FACTS

Sodium Hydroxide

Pesticide Reregistration

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for sodium hydroxide.

Use Profile

Sodium hydroxide is registered for use as a herbicide to control tree roots in sewer systems; as a fungicide and algicide for use on water-well casings; and as a disinfectant in various indoor settings. Also known as caustic soda, this corrosive substance also has many non-pesticidal uses, particularly in the rayon, film and chemical industries.

Regulatory History

Sodium hydroxide first was registered as a pesticide in 1951. Currently, seven products are registered which contain sodium hydroxide, most in combination with other pesticide active ingredients. The Food and Drug Administration (FDA) considers sodium hydroxide generally recognized as safe (GRAS) for use in food.

Under a memorandum of understanding issued in 1971, FDA evaluates the dietary risks of sanitizers used on food contact surfaces while EPA assesses the product chemistry, efficacy and applicator risks. Since sodium hydroxide is included under this agreement, EPA has deferred to FDA's assessment of dietary risks in preparing this RED.

Human Health Assessment

Toxicity

Sodium hydroxide is a widely used chemical whose toxicity has been well known for some time. It is corrosive and irritating to the skin, eyes and mucous membranes, and has been placed in Toxicity Category I (indicating the highest degree of toxicity) for acute eye and skin irritation effects.

A subchronic inhalation study showed bronchial and lung effects in rats. Chronic carcinogenicity studies using mice and rats showed no cancer effects. The chemical is not mutagenic. Human poisoning cases indicate that less than 10 grams taken orally is fatal.

Dietary Exposure

Sodium hydroxide is not used directly on food or feed, but is used on food contact surfaces and well-head casings. These uses have been evaluated by FDA under the memorandum of understanding described earlier, and have been found not to pose unacceptable dietary risks.

Occupational and Residential Exposure

Based on approved product formulation types and application methods, mixers, loaders and applicators in commercial and institutional settings may be exposed to sodium hydroxide. However, as long as label directions and precautions are followed, exposure of eyes and skin should be minimal.

Human Risk Assessment

Sodium hydroxide is corrosive and irritating to the skin, eyes and mucous membranes but does not appear to cause chronic health effects. Dietary exposure to the chemical is minimal and has been cleared by FDA. The potential for significant eye and skin exposure to mixers, loaders and applicators in commercial and institutional settings exists. However, if products are used in accordance with label precautions for eye and skin protection, worker exposure should be minimal. Therefore, the most significant human health risks posed by use of sodium hydroxide are adequately mitigated by product labeling.

Environmental Assessment

Environmental Fate

Sufficient information is available in the public literature on the fate of sodium hydroxide in the environment. No further environmental fate data are required for reregistration.

Ecological Effects

One outdoor use of sodium hydroxide, to treat sewage systems, also is regulated by State agencies through the National Pollution Discharge Elimination System (NPDES) permit program; therefore, EPA did not conduct a risk assessment for this use. Current product labeling warns that sewer treatment effluent containing sodium hydroxide may not be discharged into lakes, streams, ponds, estuaries, oceans, or public waters

without an NPDES permit. The water well casings use of sodium hydroxide is believed to result in only minimal exposure of birds, mammals and other terrestrial organisms. Current product labeling helps protect wildlife from undue exposure to sodium hydroxide.

Additional Data Required

EPA has waived all generic data requirements for sodium hydroxide except basic product identity and chemistry information. Generic data on the composition, manufacturing process and impurities of each technical source used in registered pesticide products is required for reregistration.

Product-specific data, including product chemistry and efficacy studies, also are required for reregistration.

Product Labeling Changes Required

The labels of all registered sodium hydroxide products must comply with EPA's current pesticide labeling requirements.

- In addition, manufacturing- and end-use products registered to control roots in sanitary sewer lines (except products intended solely for residential use, which are exempt) must bear the following statement:

> "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 an 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."

- 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.

- The Agency is requiring the following label statement on all end-use products to mitigate the potential for irreversible eye tissue damage: "When using this product, wear eye goggles or safety glasses."

Regulatory Conclusion

- None of the registered pesticide products containing the active ingredient sodium hydroxide are likely to cause unreasonable adverse effects in people or the environment, and all are eligible for reregistration. These products will be reregistered once the required generic data, product-specific data and revised labeling are received and accepted by EPA.

- Registered products containing sodium hydroxide as well as other active ingredients will be reregistered once the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for sodium hydroxide during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the sodium hydroxide RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about sodium hydroxide or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual sodium hydroxide products, please contact the Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-7830.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 24 hours a day, seven days a week, or fax your inquiry to 806-743-3094.

United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(H-7508W)

EPA

Reregistration Eligibility Document (RED)

SEP 30 1992

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.

SODIUM HYDROXIDE REREGISTRATION ELIGIBILITY TEAM

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Attachment C - Requirements Status and Registrants' Response Forms (Form B) plus Instructions
Attachment D - List of all Registrant(s) sent this DCI
Attachment E - EPA Acceptance Criteria and PR Notice 86-5
Attachment F - Cost Share/Data Compensation Forms

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/Industrial 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 [3]. 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. # 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
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		Use Limitations also see Abbreviations
								Allowed	Disallowed	
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. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ 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; Apps = 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

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 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. 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 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. 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					

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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 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. 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					

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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					

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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.
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1. Company name and Address 009902
IRON OUT, INC.
1515 DIVIDEND RD
FORT WAYNE IN, 46808

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."
9902-1					

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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 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	
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10700-2					

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Washington, D.C. 20460

DATA CALL-IN RESPONSE

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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 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. 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					

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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

SPECIFIC INSTRUCTIONS FOR THE DATA CALL-IN RESPONSE FORM

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

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

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

INSTRUCTIONS:

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers

(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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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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	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).

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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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 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.	

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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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*** 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).

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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 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	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.	
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*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
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Chemical # and Name
075603 Sodium hydroxide

GUIDELINE	COMMENT
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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.	

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IRON OUT, INC.
1515 DIVIDEND RD
FORT WAYNE IN 46808

2. Case # and Name
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Chemical # and Name 075603
Sodium hydroxide

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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.	
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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

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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.	
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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).

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 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
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 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
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 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
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 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
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 009902
IRON OUT, INC.
1515 DIVIDEND RD
FORT WAYNE IN, 46808

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

3. Date and Type of DCI
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 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
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 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
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 "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 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
BOYER CORPORATION
BOX 10
LA GRANGE IL 60525

2. Case # and Name
4065 Mineral bases, strong

EPA Reg. No. 500-22

3. Date and Type of DCI
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
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
BOYER CORPORATION
BOX 10
LA GRANGE IL 60525

2. Case # and Name
4065 Mineral bases, strong

EPA Reg. No. 500-22

3. Date and Type of DCI
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
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).

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
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
	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

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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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Date

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
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

13. Phone Number

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
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
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

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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
	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

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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.	

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
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, 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

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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
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.	

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

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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
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
	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

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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

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

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Name of technical material tested (include product name and trade name, if appropriate)
2.___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3.___ Name and upper certified limit for each impurity or each group of impurities present at ≥ 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

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)

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.

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.

1. Number of representative samples analyzed for all active ingredients and all impurities at ≥ 0.1%.
2. Degree of accountability or closure in analyses in item #1.
3. Chemical names of toxic impurities which were analyzed for levels <0.1%.
4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.
5. Statement of precision and accuracy of method(s) in item #4.
6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.
7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.
8. Proposed upper certified limit for each impurity present at >=0.1% and certain toxicologically significant impurities at <0.1% with brief explanation of how limits were determined.
9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).
10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color
___ Verbal description of coloration (or lack of it)
___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
___ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
___ Based on visual inspection at about 20-25° C

63-4 Odor
___ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
___ Observed at room temperature

63-5 Melting Point
___ Reported in C°
___ Any observed decomposition reported

63-6 Boiling Point
___ Reported in C°
___ Pressure under which B.P. measured reported
___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
___ Measured at about 20-25° C
___ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

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

63-12 pH

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

63-13 Stability

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

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

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

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

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, end-use product, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing and for at least 14 days.
7. Summarization of body weights
8. Summarization of gross necropsy
9. Significance of changes from the Acceptance Criteria

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

GUIDANCE FOR SUMMARIZING STUDIES

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Identify material tested (technical, end-use product, etc)
2. ____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\leq$ 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