US ERA ARCHIVE DOCUMENT

SEPA R.E.D. FACTS

Oxalic Acid

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 oxalic acid.

Use Profile

Oxalic acid is registered for use as a disinfectant to control bacteria and germs, and as a sanitizer, in toilet bowls, urinals and bathroom premises. Registered products are formulated as ready-to-use liquids or solid soluble concentrates, and are applied by sprinkling, pouring, brushing, swabbing or mopping the product onto the surface to be treated.

Oxalic acid also has many diverse, non-pesticidal, manufacturing and industrial uses including use in fabric printing and dyeing; bleaching straw hats; removing paint, varnish, rust or ink stains; and cleaning wood.

Regulatory History

Oxalic acid first was registered as a pesticide in 1957 for the current bathroom disinfectant uses, as well as use in swimming pool water systems, drainage systems, sewage systems, eating establishments (to disinfect equipment and utensils), and other sites. At present, five products containing oxalic acid are registered.

Oxalic acid is exempt from the requirement of a tolerance (or legal residue limit) when it is used as an inert ingredient in pesticide formulations that are applied to growing or harvested crops. EPA also is regulating oxalic acid under its Inerts Strategy.

Human Health Assessment

Toxicity

Oxalic acid is a substance that occurs naturally in many plants and vegetables, and also is a product of the metabolism of molds. It is a widely used chemical whose toxicity is well known. In assessing oxalic acid's risks to people, EPA relied on articles in published scientific literature.

Oxalic acid is corrosive to the eyes and skin, and has been placed in Toxicity Category I (indicating the highest degree of toxicity) for acute eye and skin irritation effects. It also is highly irritating and damaging to the respiratory system if inhaled. Acute exposure also causes stomach irritation, lowered calcium levels, effects to the nervous system and kidney damage in humans.

A subchronic inhalation study in rats showed decreased body weights, restricted growth and disrupted estrous cycles. At the highest dose, the test animals also had reduced thyroid weights and changes in iodine and hormone levels. Metabolism studies show that excess levels of oxalic acid cause kidney damage in mammals. Chronic oral intake in animals produces kidney damage and disturbances in the metabolism of calcium. A multigeneration mouse reproduction study showed reproductive effects and parental toxicity at the highest dose level.

Occupational and Residential Exposure

The potential for significant eye and dermal exposure exists when workers or homeowners apply bathroom disinfectant products containing oxalic acid and other active and inert ingredients. These products are liquid and granular formulations applied using brushes, swabs or mops. Exposure, especially to the concentrated formulations, can cause chemical burns to the skin and severe to permanent damage to the eyes.

Human Risk Assessment

Although they contain only a small amount of oxalic acid and a much greater amount of other active and inert ingredients, oxalic acid products as formulated and registered for use as bathroom disinfectants can be highly irritating and damaging to the eyes, skin and mucous membranes. Exposure to the concentrated formulations can result in chemical burns to the skin and severe to permanent eye damage. However, these risks should be low as long as product label directions and precautions are followed.

Environmental Assessment

Environmental Fate

EPA relied on data available in the scientific literature to assess the environmental fate and transport of oxalic acid used as a pesticide. Oxalic acid occurs widely in nature--it is present in the tissues of many plants and

algae, serving both to excrete and store calcium. In water, its negative ion forms complexes with a number of metal ions; and oxalic acid is immobilized as a result of this formation of complexes. Both aerobic and anaerobic conditions biodegrade oxalic acid in less than one day.

Oxalic acid, used as an indoor disinfectant, degrades readily and rapidly under both aerobic and anaerobic conditions during sewage treatment. Sewage effluents discharged to natural waters are not expected to contain oxalic acid residues from its use as a pesticide. Any oxalic acid present in the environment is the result of natural processes and not from use of the chemical as a bathroom disinfectant.

Ecological Effects

EPA did not require or evaluate ecological effects data for oxalic acid because the pesticide is only used indoors and exposure to wildlife is not expected to occur. However, three studies are being required to assess the toxicity of the pesticide to wildlife in case of a spill. The results of these studies will be used to develop product labeling statements.

Additional Data Required

EPA is requiring three acute toxicity studies on birds, freshwater fish and invertebrate species, to determine oxalic acid's toxicity hazard to wildlife in case of a transportation accident and develop appropriate product label statements. All other generic data requirements have been waived.

Product-specific data, including product chemistry and efficacy studies, also are required for reregistration of oxalic acid. Additional label precautions may be required, depending on the results of these studies.

Product Labeling Changes Required

The labels of all registered oxalic acid products must comply with EPA's current pesticide labeling requirements. The Agency may require additional label directions and precautions, depending on the results of the studies mentioned above.

Regulatory Conclusion

- The pesticide oxalic acid will not result in unreasonable adverse effects to human health or the environment, and all registered products containing oxalic acid are eligible for reregistration. These products will be reregistered once the required product-specific data and revised labeling are received and accepted by EPA.
- Registered products containing oxalic acid 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 oxalic acid during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, 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 oxalic acid 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 oxalic acid 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 oxalic acid products, please contact Arvella Farmer, Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-6939.

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.



SEPA Reregistration **Eligibility Document** (RED)

Oxalic Acid

REREGISTRATION ELIGIBILITY DOCUMENT OXALIC ACID

LIST D

CASE 4070

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

OXALIC ACID REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Branch

Phyllis Johnson

Biological Analysis Branch

Rafael Prieto

Biological Analysis Branch

Environmental Fate and Effects Division

Silvia Termes

Environmental Fate and Ground Water Branch

Bernice Slutsky

Science Analysis and Coordination Staff

Heather Mansfield

Ecological Effects Branch

Health Effects Division

Charles Frick

Chemical Coordination Branch

Pat McLaughlin

Toxicology Branch II

Judy Smith

Occupational and Residential Exposure Branch

Program Management and Suprort Division

Evelyn Alston

Information Services Branch

Registration Division

Alfred Smith

Registration Support Branch

Ruth Douglas

Arvella Farmer

Antimicrobial Program Branch Registration Support Branch

Joanne Schulte

Precautionary Labeling Branch

Special Review and Reregistration Division

Tom Luminello -

Accelerated Reregistration Branch

Carol Stangel

Policy Planning and Operations Staff

Policy and Special Projects Staff

Kennan Garvey

Office of General Counsel:

Steve Wolfson

Office of Compliance Monitoring:

Beverly Updike

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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

HDT Highest Dose Tested

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.

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 death 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.)

No Observed Effect Level. Dose level not associated NOEL

with toxic effects.

Office of Pesticide Programs OPP

ppm Parts Per Million

RED Reregistration Eligibility Document

TD Toxic Dose. The dose at which a substance produces a toxic effect.

Micro-grams μg

EXECUTIVE SUMMARY

This Reregistration Eligibility Document (RED) addresses pesticide uses of oxalic acid. Products containing oxalic acid are currently registered as disinfectants (bactericides/germicides) and sanitizers. It is formulated as a soluble concentrate solid and ready-to-use liquid for use in toilet bowls, urinals, and bathroom premises. All products containing oxalic acid 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 published scientific literature and other relevant information supporting the reregistration of oxalic acid. The conduct and submission of commonly required generic toxicology, human exposure, and environmental effects studies have been waived by EPA due to the availability of adequate published information. This information supports the conclusion that use of oxalic acid pesticide products according to label instructions will not result in unreasonable adverse effects to human health or the environment.

Accordingly, the Agency has determined that all products containing oxalic acid 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. End-use products containing oxalic acid in combination with other active ingredients under reregistration 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 ingredients 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 oxalic acid. The document consists of six sections. Section I is the introduction. Section II describes oxalic acid, 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 oxalic acid. Section V covers actions required by registrants of 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.

¹EPA's reviews of data used 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: Oxalic Acid

CAS Registry Number: 144-62-7

OPP Chemical Code:

009601

Empirical Formula:

C₂H₂O₄

B. Use Profile

1. Type of Pesticide: Disinfectant; sanitizer

a. Pests Controlled: Common human and

environmental bacteria

2. Formulation Types Registered

a. Type:

End Use

b. Forms:

Solid Soluble Concentrate,

Ready-to-use Liquid

3. Use Practices and Limitations:

a. Use Sites:

Bathroom Premises/Hard Surfaces, Toilet

Bowls (Interior Surfaces), Urinals (Interior

Surfaces)

b. Use Practices:

Pour-on, Sprinkle, Swab Brush, Swab,

Mop as needed

c. Use Limitations:

Use as needed

C. Regulatory History

The Agency first registered a product containing oxalic acid in 1957. Initial registered uses included swimming pool water systems, drainage systems, sewage systems, eating establishments (equipment and utensils), commercial, institutional and industrial areas/premises, bathroom premises, toilet tanks or water closets, and toilet bowls and urinals. Currently, only toilet bowl, urinal, and use on bathroom premises

remain for the five active products.

While this presentation of the Agency's scientific and regulatory position is limited to the reregistration of eligibility of oxalic acid as a pesticide active ingredient, the Agency has also regulated oxalic acid as an inert ingredient in formulations of other pesticide products.

Oxalic acid has been exempt by the Agency from the requirement of tolerances of residues [40 CFR 180.1001(C)] when used as an inert (or occasionally active) ingredient in pesticide formulations applied to growing or harvested crops. This exemption applies specifically to its use as a calcium-chelating hard water inhibitor and this use is limited to no more than two pounds of oxalic acid per acre. Additionally, the Office of Pesticide Programs (OPP) of the Agency has included oxalic acid as an inert ingredient under its Inert Strategy. In this strategy, OPP prioritized 1200 existing inert ingredient chemicals into four lists of descending toxicological concern. OPP placed oxalic acid on List Three (unknown toxicity). Now, with the current toxicological assessment, Section III below, OPP will likely move oxalic acid to the lowest chemical category of toxicological concern, List Four.

III. SCIENCE ASSESSMENT OF OXALIC ACID

The Agency has reviewed the scientific data base for oxalic acid. Information considered is primarily from published literature. Sources used are cited in Appendix C.

A. Chemistry Assessment

1. Physical Properties of Oxalic Acid

Oxalic acid occurs naturally in many plants and vegetables, notably in those of the Oxalis and Rumex families, where it occurs in the cell sap of the plant as the potassium or calcium salt. It is also a product of the metabolism of the many molds. Several mold species of Penicillium and Aspergillus convert sugar into calcium oxalate with 90% yields under optimum conditions.

Oxalic acid occurs as a white-to-colorless and odorless solid. The molecular weight is 90.04. Oxalic acid is very soluble in water and ethanol, slightly soluble in ether, insoluble in benzene, chloroform and petroleum ether. The pH of dihydrate oxalic acid is 1.3 in a 0.1 M solution of water. Oxalic acid is a dibasic acid and has two dissociation constants. The octanol/water partition coefficient is inapplicable since neither its dihydrate nor anhydrate is soluble in lipophilic organic solvents.

2. Manufacturing Methods and Non-Pesticidal Industrial Uses

Oxalic acid was formerly manufactured by fusion of cellulose matter, e.g sawdust, with sodium hydroxide or by oxidation. It is now made by passing carbon monoxide into concentrated sodium hydroxide or by heating sodium formate in the presence of sodium hydroxide or sodium carbonate.

Oxalic acid is used as an analytical reagent; in calico printing and dyeing; for bleaching straw (hats) and leather; removing paint or varnish, rust or ink stains; and for cleaning wood. It is also used in manufacturing oxalates, blue ink, celluloid, dyes, metal polishes, indigo dyeing, in purifying methanol for decolorizing crude glycerol, and for stabilizing hydrocyanic acid. As a general reducing agent it is used in ceramics and pigments, in metallurgy as a cleanser, in the paper industry, in photography, in process engraving, in the rubber manufacturing industry, in making glucose from starch, and as a condensing agent in organic chemistry. [Merck Index, citation 6784, page 991, Tenth Edition, 1983].

B. Human Health Assessment

EPA relied on two sources of toxicological information for its human risk assessment of oxalic acid. Refer to Appendix C for the citations.

1. Acute Toxicity

TEST	RESULT	CATEGORY
Oral LD ₅₀	over 1000 mg/kg	Ш
Inhalation	very irritating	2
Eye effects	corrosive	I
Skin effects	corrosive	I

Reports of acute oral tests with technical grade oxalic acid gave an LD₅₀ in rats of 7500 mg/kg, an LDlo in dogs of 1000 mg/kg, an LD₅₀ greater than 1000 mg/kg in ruminants, and an LD₅₀ over 300 mg/kg in gravid rats. The acute effects include gastric hemorrhage, central nervous system depression,

² Data for the classification of oxalic acid when inhaled are unavailable, but will be generated for the end-use products.

convulsion, coma, and kidney damage. The probable oral lethal dose for humans has been estimated as 50 to 500 mg/kg. Human symptoms include burning pain in the mouth and throat, gastrointestinal irritation, hypocalcemia, nervous system effects, and kidney damage.

Oxalic acid produces severe irritation on skin and eyes, and chemical burns. Oxalic acid is considered highly irritating and damaging to the respiratory system on inhalation.

The acute toxic effects of oxalic acid relate to three mechanisms of action: (a) a strong irritant effect on the skin, eyes, mucous membranes, and any exposed body areas; (b) a hypocalcemic effect from the binding of free calcium in the body; (c) kidney toxicity from deposition of calcium oxalate in renal tubules.

Based on worker protection information, 0.14 mg/kg/day has been estimated as the human allowable exposure to oxalic acid from all sources over a 24-hour period.

2. Subchronic Toxicity

Rats fed diets with 2.5 or 5.0 percent oxalic acid (approximately 1250-1500 or 2500-3000 mg/kg/day) for 70 days had decreased body weight and restricted growth, as well as disrupted estrous cycles. Rats given 2500-3000 mg/kg/day of oxalic acid in the diet had reduced thyroid weight, along with changes in iodine and hormone levels. The NOEL for subchronic dietary exposure is less than 1250 mg/kg/day.

3. Metabolism

Oxalic acid ingested by mammals chelates free calcium ions and is excreted as calcium oxalate. Excess levels cause deposition of calcium oxalate in kidney tubules and renal damage. Oxalate can be formed in the liver from a number of metabolic substrates, including glycine and ethylene glycol, by way of glyoxalate, the immediate precursor of oxalate.

4. Chronic Toxicity

Chronic oral intake in animals produces kidney tubule damage and disturbances in calcium metabolism. Intake of

excess oxalate is most frequently found in sheep and cattle due to their grazing on oxalate-rich plants. In humans, chronic skin exposure to oxalic acid has caused cyanosis and gangrenous changes from localized absorption.

5. Mutagenicity

Oxalic acid is highly toxic to cells and to bacteria, which makes it very difficult to conduct mutagenicity studies. None have been reported.

6. Reproduction and Developmental Toxicity

National Toxicology Program sponsored a multigeneration reproduction study in CD-1 mice with oxalic acid dihydrate. Doses of 0, 0.05, 0.1, or 0.2 percent were given in the drinking water over two generations using the continuous breeding protocol. The effects noted at the 0.2 percent dose included reduced body weight gain in females, decreased live pup weight, decreased litters per mating pair, reduced number of live pups per litter, decreased prostate gland weight in parents, changes in parental kidney weights, and more abnormal sperm. No apparent reproductive effects were observed at lower doses. The NOELs for parental toxicity and reproductive toxicity were 0.1 percent and the LELs were 0.2 percent. Rats were given 0, 0.18, or 0.23 mg/kg/day of oxalic acid by gavage during pregnancy. There were renal oxalosis and gastritis, as well as slightly increased mortality, in the dosed dams. There was some decrease in mean litter size but no teratogenic effects in the pups.

7. Occupational and Residential Exposure

Products containing oxalic acid are applied using brushes, swabs, and mops. Based on the application methods and the formulation types, the potential for significant eye and dermal exposure exists during use of concentrated solutions and granular solid formulations. Dermal exposure to concentrated solutions of oxalic acid will result in chemical burns and may cause severe to permanent damage to the eye.

8. Human Risk Assessment

The toxicological data published in the open literature for

oxalic acid are adequate to assess the risk to humans. The risk of chemical burns from dermal exposure to workers and homeowners is expected to be low under reasonable pesticide/biocide use following label instructions. Exposure concerns are to be addressed by appropriate label precautions for eye, dermal, and respiratory handling activities. Appropriate label precautions for products will be determined upon receipt of acute toxicology studies on the end-use products.

C. Environmental Fate and Ecological Effects Assessment

1. Environmental Fate Assessment

The Agency is relying on data available in the scientific literature to assess the environmental fate and transport of oxalic acid as used as a pesticidal compound.

a. Environmental Fate and Transport

Oxalic acid occurs widely in nature. It is present in many plant and algal tissues, constituting as much as 50% dry weight in some organs; oxalic acid serves as both excretory and storage functions for calcium (1). In aqueous solution, oxalic acid dissociates in a stepwise manner. At 25° C and zero ionic strength, the first dissociation constant (K_1) of oxalic acid has been reported as 5.3×10^{-2} and the second dissociation constant (K_2) as 5.0×10^{-5} (2, 3, 4).

A very important aspect of the chemistry of oxalic acid in aqueous media is the ability of the oxalate anion to form complexes with a large variety of metal ions, which include the alkaline earths, first-, second-, and third-row transition metals, the lanthanides, and the actinides (5, 6, 7). In the environment, oxalato complexes and oxalate salts of importance are those of calcium, magnesium, aluminum, and iron (8, 9).

Plant debris is composed predominantly of the relatively insoluble calcium oxalate, which appears to constitute the major fraction of particulate oxalates in water/sediments habitats (9). Oxalic acid is immobilized as the result of the formation of complexes and/or insoluble salts.

Oxalic acid (or the oxalate) anion is not expected to degrade by direct photolysis since these species do not absorb energy in the visible region (10). Any photodegradation that may be observed in the

environment would involve indirect photolysis. Oxalate is the C-2 organic material most highly and readily oxidized by microorganisms. Oxidation by Pseudomomas oxalacticus to glyoxylate is well documented and proceeds via several intermediates, but the final oxidation product is carbon dioxide. Biodegradation by several other microorganisms can also occur (11, 12). Both aerobic and anaerobic conditions biodegrade oxalate in less than one day (2). In natural aquatic habitats oxalato complexes and oxalate salts also mineralize in less than one day, although rates of mineralization observed in littoral sediments have been higher than rates observed in pelagic sediments of lakes (8).

Sewage microorganisms have been reported to mineralize oxalate even when complexed, but there is evidence that the rate of mineralization is dependent on the speciation (i.e. the type of metal and the number of oxalato ligands complexed to it) and the type of microorganism; mineralization can occur in less than a day (7).

b. Environmental Fate Assessment

Oxalic acid, used as an indoor disinfectant, is expected to degrade readily and rapidly under both aerobic and anaerobic conditions during sewage treatment. Sewage effluents discharged to natural waters would not be expected to contain oxalic acid residues from its use as a pesticide. Any oxalic acid or oxalates that may be present in the environment (soils, waters) are the result of natural processes (microbial excretion, plant debris) and not from the use of oxalic acid as a bathroom disinfectant.

2. Ecological Effects Assessment

No ecological effects data have been evaluated for oxalic acid.

a. Ecological Hazard

Currently registered uses for oxalic acid are indoor. Exposure to wildlife under typical conditions of use would not occur. Therefore, the Agency is not requiring ecological effects data for the purpose of reregistration. For these reasons, no environmental risk assessment has been performed for oxalic acid under its current use pattern. However, three studies to assess toxicity endpoints in the case of a spill are required and will be used for product labeling statements. These three

studies are avian dietary LC₅₀, freshwater fish LC₅₀, and freshwater invertebrate LC₅₀.

b. Ecological Effects Assessment

Since all of the uses of oxalic acid are indoor residential, outdoor exposure would most likely be the result of spillage during transport or sewage leaks, although sewage effluents would not be expected to contain oxalic acid used as a pesticide for the reasons cited in the environmental fate assessment. Therefore, a risk assessment will not be performed for oxalic acid under this use pattern.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR OXALIC ACID

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 oxalic acid are eligible for reregistration. The Agency has waived submission of all generic data requirements for its risk assessment and reregistration eligibility decisions. The Agency has completed its review of all available information, and has determined that the data are sufficient to support reregistration eligibility of products containing oxalic acid. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of oxalic acid 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 oxalic acid and to determine that these uses can be used without resulting in unreasonable adverse effects to humans and the environment. Further, the Agency is requiring three acute toxicology studies on birds, freshwater fish, and invertebrate species to confirm hazard potential for labeling in case of transportation accidents. Refer to Section V A below, for these data requirements. Therefore, the Agency finds that products containing oxalic acid 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 oxalic acid 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 oxalic acid, if new information comes

to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

B. Eligibility Decision

The Agency has sufficient information on the human health effects of oxalic acid and on its potential for causing effects in the environment when used to control bacteria in indoor residential areas. The Agency has concluded that there are no adverse effects to humans or the environment and that products containing oxalic acid for these uses are eligible for reregistration. The Agency has determined that oxalic acid-containing products, labelled and used in accordance with the terms of this Reregistration Eligibility Document, will not pose unreasonable effects to humans or the environment.

V. ACTIONS REQUIRED BY REGISTRANTS OF END-USE PRODUCTS

This section is designed to assist the registrant by providing data requirements for the reregistration of end-use products.

A. Additional Generic Data Requirements

The generic data base supporting the reregistration of oxalic acid-containing products has been reviewed and determined to be substantially complete. Additional data to characterize the toxicity to wildlife for labelling purposes is required. These requirements are part of the generic Data Call-In and are listed in Appendix F.

B. Determination Of Eligibility

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

1. Product Specific Data Requirements

The product specific data requirements are stated in Attachment C of Appendix G.

2. Labeling Requirements For End-Use Products

The labels and labeling of all products must comply with the Agency's current regulations and requirements. Follow the instructions in the Product

VI APPENDICES

Reregistration Handbook with respect to labels and labeling.

3. Labeling Requirements For Manufacturing-Use Products

No manufacturing-use products are registered.

APPENDIX A

Use Patterns Subject to Reregistration

December 9,

APPENDIX	A.	Case 407	4070, Chemical 009601	ical ()9600		Oxalic A	Acid			
Application Type, Application Timing, Application Equipment, Surface	Fera	Minimum Application Rate fibrin Att	Meximum Application Rete (opm Al)	Max. # Apps.	Man, # Apps. @ Man, Rete	g g 5	Min. Interval Between Apps. @ Max. Rate	Restricted Entry Interval	8 =	Geographic Livritations	Use Pattern (imitations labo ase abbreviations)
					•		Devel	Dayel	Abours	Diedemen	
USES ELIGIBLE FOR REREGISTRATION											
NONFOOD/NONFEED USES											
SITE: Bathroom Premises/Hard Surfaces (U	JSE GRO	(USE GROUP: INDOOR RESIDENTIAL)	RESIDENTIAL								
Pour-on, Not on Label, Brush, Hard	RTU	15,000 W	15,000 W	SN	NS	NS	NS	NS	A A	A A	10 minutes contact time
Pour-on, Not on Label, Swab, Hard	RTU	12,000 W	12,000 W	NS	SN	NS	NS	SN	₹	AM	NS
SITE: Toilet Bowls (Interior Surfaces) (U	SE GRO	(USE GROUP: INDOOR RESIDENTIAL	RESIDENTIAL	_							
Brush-on, Not on Label, Brush, Hard	RTU	20,000 W	20,000 W	NS	NS	NS	NS	NS	ΑN	₹ X	NS
Pour-on, Not on Label, Brush, Hard	RTU	15,000 W	30,000 W	NS	NS	NS	SN	SN	٧	A A	15 minutes contact time
Pour-on, Not on Label, Mop, Hard	RTU	12,000 W	12,000 W	NS	NS	SN	SN	SN	۷ ۷	A A	10 minutes contact time
Sprinkle, Not on Label, Brush, Hard	SC/S	009 w	600 W	SN	NS	NS	NS	NS	Ą	AN AN	
Sprinkle, Not on Label, Swab, Hard	SC/S	600 W	009 W	NS	NS	NS	NS	NS	ž	٧×	
Pour-on, Not on label, Brush, Hard	RTU	15,000 W	15,000 W	SN	NS	NS	NS	NS	Ą.	ΑN	10 minutes contact time
Swab, Not on Label, Mop, Hard	RTU	21,200 W	21,200 W	SN	SN	NS	NS	NS	۷ ۷	Ϋ́	10 minutes contact time
SITE: Urinals (Interior Surfaces) (US	SE GRO	(USE GROUP: INDOOR!	OR RESIDENTIAL)								
Mop, Not on Label, Mop, Hard	RTU	12,000 W	12,000 W	NS	NS	NS	NS	NS	NA NA	٧	SN
Pour-on, Not on Label, Mop, Hard	RTU	15,000 W	15,000 W	NS	NS	NS	SN	NS	AN	NA V	10 minutes contact time
Swab, Not on Label, Bowl Mop, Hard	RTU	30,000 W	30,000 W	NS	NS	NS	· NS	NS	Š	A A	NS

-:

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APPEND	APPENDIX A . Case		4070, Chemical 009601 [Oxalic Acid]	cal (960	17 [0]	xalic A	cid]			
Application Type, Application Timing, Application Equipment, Surface	Form	Minimum Application Rate form All	Maximum Apphication Rate (ppm Al)	Men. / Apps.	Max. # Abps. @ Max. Rate	Max. # Apps. @ Max. Rate	Min, Interval Between Apps. @ Max. Rets	Restricted Entry Interval	Geographic Limitations	* 5	Use Pattern Limitations (also see abbreviations)
							(Deys)	(Deys)	Alterned	Disafforward	
SITE: Urinals (Interior Surfaces) (U	SE GROU	JP: INDOOR	(USE GROUP: INDOOR RESIDENTIAL) (Continued from previous page)	Conti	nued fro	m previ	ous page)				
Swab, Not on Label, Mop, Hard	RTU	21,200 W	RTU 21,200 W 21,200 W NS	SN	NS	NS	NS	NS	۸۸	NA NS	NS
										1	

Abbreviations used:

Header: Max = Maximum; Min = Minimum; Apps = Applications; Al = Active Ingredient Form: RTU = Ready To Use Liquid; SC/S = Solid Soluble Concentrate Rate: NC = Not Calculated; W = ppm Calculated by Weight In general: NS = 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 oxalic acid covered by this Reregistration Eligibility document. It contains generic data requirements that apply to oxalic acid 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. <u>Data Requirement</u> (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set 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. <u>Use Pattern</u> (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. <u>Bibliographic citation</u> (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Oxalic Acid

PRODUCT	PRODUCT CHEMISTRY	USE	BIBLIOGRAPHIC
61-1	Chemical Identity	0	MRID 41981701
61-2(a)	Beginning Materials and Manuf Process	0	MRID 41981701
61-2(b)	Formation of Impurities	0	MRID 41981701
62-1	Preliminary Analysis	0	MRID 41981702
62-2	Certified Limits	0	MRID 41981702
62-3	Analytical Methods	0	MRID 41981702
63-2	Color	0	MRID 42054001
63-3	Physical State	0	MRID 42054001
63-4	Odor	0	MRID 42054001
63-5	Melting Point	0	MRID 42054001
63-6	Boiling Point	0	MRID 42054001
63-7	Density	0	MRID 42054001
63-8	Solubility	0	MRID 42054001
63-10	Dissociation Constant	0	MRID 42054001
63-11	Octanol/Water Partition Coefficient	O	MRID 42054001
63-12	pH	0	MRID 42054001
63-13	Stability	0	•
ENVIRON	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.

OCCUPATIONAL EXPOSURE

EPA waived 40 CFR Part 158 generic data requirements for reasons discussed in Section III.

ECOLOGICAL EFFECTS

toxicity studies on avian, fish, and aquatic invertebrate acute toxicity to assess product label needs for potential accidents. EPA waived 40 CFR Part 158 generic data requirements for reasons discussed in Section III. However, we are requiring three acute

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Oxalic acid

- 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.

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FOOTNOTES

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TOXICOLOGY REFERENCES

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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 oxalic acid. 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 oxalic acid 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. Oxalic Acid 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

	United	States Enviror Washingto	mental Protection Agency n, D.C. 20460 L-IN RESPONSE		Form Approved OMB No. 2070-0107 Approval Expires	Pag of 1 form Approved OMB No. 2070-0107 Approval Expires 12-31-92
INSTRUCTIONS: Please type or print in Use additional sheet(s) if necessary	INSTRUCTIONS: Please type or print in ink. Use additional sheet(s) if necessary	Please read carefully	the attached instructions and supply the information requested on this form.	information requested o		
1. Company name and Address RECKITT & COLEN 1655 VALLEY RD WAYNE NJ 07474	and Address 000 & COLEMAN HOUS LLEY RD	000475 HOUSEHOLD PRODUCT	Case # and Name 4070 Oxalic acid, a Chemical # and Name 009601 Oxalic acid	and salts	3. Date and Type of DCI GENERIC	
4. EPA Product Registration	5. I wish to cancel this product regis- tration volun- tarily	6. Generic Data 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7. Product Specific Data 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."
475-69 475-199 475-2 2 5						
8. Certification I certify that the statements made on this form and all atil acknowledge that any knowingly false or misleading state or both under applicable law. Signature and Title of Company's Authorized Representative	tatements made on the syknowingly false on the sale law.	tachments ment may	are true, accurate, and complete. be punishable by fine, imprisonment	9. Date		
10. Name of Company Contact	Contact			11. Ph	11. Phone Number	

Approval Expires 12-31-92 Fune 1 of 1 OMB No. 2070-0107 9. Registrant Response Form Approved 3. Date and Type of DCI GENERIC INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. 13. Phone Number mos. mos. mos. 8. Time Frame 11. Date 127 4070 Oxalic acid, and salts 7. Test Substance TGA I TGA I TGAI United States Environmental Protection Agency REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE 009601 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. Chemical # and Name 6. Use Pattern Washington, D.C. 20460 Case # and Name 000 Oxalic acid Progress Reports RECKITT & COLEMAN HOUSEHOLD PRODUCTS 000475 Signature and Title of Company's Authorized Representative Fish toxicity rainbow trout Acute avian diet, quail Invertebrate toxicity 5. Study Title Use additional sheet(s) if necessary 1. Company name and Address 1655 VALLEY RD WAYNE NJ 07474 12. Name of Company Contact 10. Certification 4. Guideline Requirement Number 71-2(a) 72-1(c) 72-2(a)

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

* COMMENTS FOR GUIDELINE REQUIREMENTS

4070 Oxalic acid, and salts chemical # and Name 009601 Oxalic acid Case # and Name

COMMENT

GUIDEL INE

Required to assess the toxicity of the chemical to wildlife in case of a spill. 71-2(a)

Required to assess the toxicity of the chemical to wildlife in case of a spill. 72-1(c)

Required to assess the toxicity of the chemical to wildlife in case of a spill. 72-2(a)

Approval Expires 12-31-92 requirements on the attached 7b. My product is an EUP and form entitled "Requirements Status and Registrant's Response." I agree to satisfy the EUP of 1 OMB No. 2070-0107 _ Form Approved Pa 3. Date and Type of DCI GENERIC Please read carefully the attached instructions and supply the information requested on this form. 11. Phone Number requirements on the attached form entitled "Requirements Status and Registrant's 7a. My product is an MUP and I agree to satisfy the MUP 7. Product Specific Data 9. Date and salts Response." 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." United States Environmental Protection Agency Oxalic acid, l 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 Chemical # and Name 009601 Washington, D.C. 20460 DATA CALL-IN RESPONSE Case # and Name Oxalic acid 4070 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis-tration number listed below. ۶. Signature and Title of Company's Authorized Representative_ 6. Generic Data 90040 011292 INSTRUCTIONS: Please type or print in ink. 6423 BANDINI BOULEVARD 5. I wish to cancel this product regis-tration volun-tarily CITY OF COMMERCE CA Use additional sheet(s) if necessary or both under applicable law. Company name and Address 10. Name of Company Contact CHEMIFAX 8. Certification 4. EPA Product Registration 11292-3

	United States Environme Washington,	Environmental shington, D.C.	Protection Agency 20460	;y		Pc 1 Of 1 Form Approved
	REQUIREMENTS STATUS	AND	REGISTRANT'S RESPONSE	Щ		OMB No. 2070-0107
INSTRUCTIONS: Please type or print in ink. Use additional sheet(s) if necessary	type or print in ink. Please read carefully ts) if necessary	ully the attached	the attached instructions and supply the information requested on this form.	e information requ	sted on this form.	Approvat Expires 12-51-92
1. Company name and Address CHEMIRAX 6423 BANDINI B(CITY OF COMMER(FAX BANDINI BOULEVARD OF COMMERCE CA 90040	2. Case # and Name 4070 OXA Chemical # and Oxalic acid	Case # and Name 4070 Oxalic acid, and Chemical # and Name 009601 Oxalic acid	d salts	3. Date and Type GENERIC	Type of DCI
4. Guideline Requirement Number	5. Study Title	Progress Reports	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
71-2(a) * 72-1(c) * 72-2(a) *	Acute avian diet, quail Fish toxicity rainbow trout Invertebrate toxicity		000	TGA1 TGA1 TGA1	12 mos. 12 mos. 12 mos.	
10. Certification			-			
I certify that the state I acknowledge that any ior both under applicable	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.	nents are true, ac may be punishable	curate, and complete. by fine, imprisonment		11. Date	
Signature and Title of (Signature and Title of Company's Authorized Representative					
iz. Mame of Lompany Contact	tact				13. Phone Number	

1 of 1 Pac Required to assess the toxicity of the chemical to wildlife in case of a spill. Required to assess the toxicity of the chemical to wildlife in case of a spill. Required to assess the toxicity of the chemical to wildlife in case of a spill. United States Environmental Protection Agency * COMMENTS FOR GUIDELINE REQUIREMENTS Washington, D.C. 20460 4070 Oxalic acid, and salts Chemical # and Name 009601 Oxalic acid COMMENT Case # and Name 72-1(c) 72-2(a) 71-2(a) GUIDEL INE

Attachment A Chemical Status Sheet

OXALIC ACID: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 oxalic acid. 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 Oxalic Acid 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 oxalic acid are contained in the <u>Requirements Status and Registrant's Response</u>, Attachment C. The Agency has concluded that additional product chemistry data on oxalic acid are needed. These data are needed to fully complete the reregistration of all products containing oxalic acid.

<u>INQUIRIES AND RESPONSES TO THIS NOTICE</u>

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Tom Luminello at (703) 308-8075.

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

Tom Luminello, Chemical Review Manager Accelerated Reregistration Branch Special Review and Registration Division (H7508-W) Office of Pesticide Programs U.S. Environmental Protection Agency Washington, D.C. 20460

RE: Oxalic Acid RED

Attachment B Generic DCI Response Forms (Form A) plus Instructions

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 <u>Requirements Status and Registrant's Response Form</u> 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 <u>Requirements Status and Registrants Response Form</u> 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 <u>Requirements Status and Registrant's Response Form</u> 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

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

- Item 1-4. Already completed by EPA.
- Item 5. If you wish to voluntarily cancel your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA registration numbers of your source(s); you would not complete the "Requirements Status and Registrant's Response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.
- Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."
- Item 7b. For each end-use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with Option 7 (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

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

- 3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.
- 4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.
- 5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (Upgrading a Study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.
- 6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.
- 7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request,

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

Items 10-13. Self-explanatory.

NOTE:

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

Attachment D List of all Registrant(s) sent this DCI

List of All Registrants Sent .is Data Call-In Notice

		Zip	90040
		City & State	WAYNE NJ PHILADELPHIA PA CITY OF COMMERCE CA
		Address	1655 VALLEY RD 2211 N AMERICAN STREET 6423 BANDINI BOULEVARD
200		Additional Name	
ğ	Oxalic acid	Company Name	RECKITT & COLEMAN HOUSEHOLD PRODUC CANTOL INC CHEMIFAX
Case # and Name 4070 Oxalic	009601 0	Company Number	000475

EPA'S BATCHING OF OXALIC ACID 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 oxalic acid, 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 oxalic acid were batched together. It was felt that the high percentage of oxalic acid 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 Oxalic acid & Other Active Ingredients	Formulation Type
11292-3	1.2% Oxalic Acid; 21.8% Hydrochloric Acid	Liquid
475-225	1% Oxalic Acid; 81% Sodium Bisulfate	Granular
475-69	2% Oxalic Acid; 7% Hydrochloric Acid	Liquid
475-199	2% Oxalic Acid; 7% Hydrochloric Acid; 0.10 BTC 2125M	Liquid
5664-4	3% Oxalic Acid; 8.5% Phosphoric Acid 5% Sulfonic Acid 1.2% Sodium Xylene Sulfonate 1% Gluconic Acid 1% Citric Acid	Liquid