REREGISTRATION ELIGIBILITY DOCUMENT

PROPIONIC ACID, AND SALTS

LIST D

CASE 4078

SEPTEMBER 1991

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

TABLE OF CONTENTS

GLOSSARY OF TERMS AND ABBREVIATIONS

CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
LEL	Lowest Effect Level
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the EPA.
ppm	Parts per Million
RED	Reregistration Eligibility Document

Executive Summary

This Reregistration Eligibility Document addresses pesticide uses of propionic acid. Propionic acid-containing products are currently registered for use in stored grains for animal and human consumption, for forage preserved as hay, drinking water for livestock and poultry, grain storage areas and poultry litter. All products containing propionic acid as an active ingredient and registered for these uses are eligible for reregistration.

The EPA has conducted a review of the scientific data base and other relevant information supporting the reregistration of propionic acid and has determined that the data base is sufficient to allow the EPA to conduct reasonable risk assessments. The data available to the EPA support the conclusion that the currently registered uses of propionic acid will not result in unreasonable adverse effects to the environment or human health. The Agency has conducted a tolerance reassessment for propionic acid and our conclusions are discussed in Section B.2.

Propionic acid is exempt from the requirement of a tolerance when used as a fungicide for post-harvest application on certain grains and hays (40 CFR 180.1023). The Agency intends to establish exemptions from tolerances for meat, milk, poultry, and eggs as a result of application to livestock and poultry drinking water, poultry litter, and storage areas for silage and grain.

Accordingly, the EPA has determined that all products containing propionic acid as the active ingredient are eligible for reregistration and will be reregistered when appropriate labeling and/or product specific data are submitted and/or cited. Before reregistering each product, the EPA is requiring that product specific data and revised labeling be submitted by the registrants within eight months of the issuance of this document. In an effort to reduce the time, resources, and number of animals needed to fulfill the acute toxicology data requirements for propionic acid containing end use products, the EPA has "batched" products considered to be similar with respect to acute toxicity testing requirements. After reviewing these data and the revised labels the EPA will determine whether or not 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 EPA will reregister the product. Any end-use products containing propionic acid in combination with other active ingredients will not be reregistered until the REDs for all active ingredients contained in that product are issued.

I. INTRODUCTION

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

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products, section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," sections 4(g)(2)(C) and (D). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the 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 3(c)(5).

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

---

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

II. ACTIVE INGREDIENT COVERED BY THIS REREGISTRATION ELIGIBILITY DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

Chemical Name: Propionic Acid

CAS Number: 79-09-4

Office of Pesticide Programs Chemical Code Number: 077702

Empirical Formula: CH_3CH_2COOH

B. USE PROFILE

Type of Pesticide:

Fungicide and Bactericide

Pests Controlled:

Fungi (molds), bacteria

Registered Use Patterns and Sites:

Indoor Food: stored high moisture grains (oats, corn, barley, wheat, and sorghum), hay (alfalfa, clover, timothy, vetch, cowpeas, sudan grass, peavine, rye grass, peanut, orchard grass, lespedeza, fescue, bromegrass, lupines, soybean, Bermuda grass and bluegrass), livestock and poultry drinking water, storage areas for silage and grain, and poultry litter.

Formulation Types Registered:

Liquid - Ready to Use (RTU) at 39.2 to 100% active ingredient (a.i.)

Soluble Concentrate/Liquid (SC/L) at 68.5% a.i.

Methods of Application:

Grain and hay: Propionic acid is applied undiluted to grain and hay with a low pressure spray system equipped with adequately arranged and calibrated nozzles to

provide desired coverage to grain as it is moved into storage, or to hay just prior to baling and stacking. The application rate is 8 - 31 pounds/ton of the active ingredient.

Drinking water (Poultry, Livestock): Add undiluted product directly to drinking water.

Poultry litter: Dilute product with water and apply to surface of litter.

Silage and grain storage area surfaces: Dilute product with water and apply to surfaces of storage areas.

C. REGULATORY HISTORY

EPA first registered propionic acid-containing products in the early 1970's. The currently registered products are used as fungicides and bactericides in the sites identified in Section II. B. above. In 1975 EPA exempted propionic acid from tolerances for residues following post-harvest application in grains or hays. (40 CFR 180.1023). Propionic Acid is also exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c). Propionic acid is Generally Recognized As Safe (GRAS) (21 CFR 184.1081), by FDA for use in food.

Propionic acid products may be used for both human food and animal feed. However, propionic acid can impart an off odor and taste to a treated commodity.

III. EPA ASSESSMENT OF ACTIVE INGREDIENT

The EPA has reviewed the scientific data base for propionic acid. Based on the evaluation of these data, the EPA has determined that there is no need to request additional data on the active ingredient.

A. DESCRIPTION OF ACTIVE INGREDIENT AND ASSESSMENT OF PRODUCT CHEMISTRY

Propionic acid naturally occurs in animals and in dairy products in small amounts. It can be obtained from natural gas by the Fischer-Tropsch process, as a byproduct in the pyrolysis of wood, and by the action of microorganisms on a variety of materials in small yields. Very pure propionic acid can be obtained from propionitrile (Merck).

Propionic acid is a colorless, oily liquid at room temperature with a rancid, pungent odor. The molecular weight is 74.08. The boiling point at atmospheric pressure is 141°C and the melting point is -22.4°C. Propionic acid is completely soluble in water, ethanol, chloroform, and diethyl ether. The specific gravity is 0.99 at 20°C. The vapor pressure is 3 mm Hg at 20°C. The dissociation constant is 1.32×10^{-5} at 25°C and the octanol water partition coefficient is 2.1. Based on the dissociation constant propionic acid has a pH around 5 (-log K=4.87).

B. HUMAN HEALTH ASSESSMENT

1. Toxicology

The toxicological data base on the active ingredient propionic acid is adequate and will support reregistration eligibility. All toxicology data requirements are satisfied. No further data on the active ingredient are required by EPA.

a. Acute Toxicity

Contact with concentrated solutions of propionic acid may cause local damage to skin, eye, or mucosa. Tissue necrosis was caused by 10 mg/24 hr with propionic acid in a rabbit skin irritation test, but the same quantity of propionic acid as a 10 percent solution in acetone had little effect (9). The acid has been called moderately toxic for rabbits but corrosive for guinea pigs in skin irritation tests (10). Rats survived an eight hour exposure to concentrated vapor of propionic acid (10).

The table below summarizes the toxicity values and categories of technical propionic acid (9,6).

TOXICITY ROUTE	VALUE	CATEGORY
ACUTE ORAL	> 2 G/KG	III
ACUTE DERMAL	> 2 G/KG	III
ACUTE INHALATION	> 0.5 THROUGH 5 MG/LITER	III
EYE IRRITATION	CORROSIVE	I
DERMAL IRRITATION	CORROSIVE	I
SKIN SENSITIZER	N/A	NO

b. Subchronic Toxicity

Although no subchronic data are available on propionic acid itself, data on calcium and sodium propionate can be used to assess subchronic toxicity. When rats were fed calcium or sodium propionate at 1 percent of the diet (equivalent to about 750 mg/kg/day of propionic acid) for 4 weeks followed by 3 percent (equivalent to about 1200 mg/kg/day propionic acid) for 3 weeks, they had no changes in weight gain compared to controls (11). Rats fed 5 percent propionic acid in the diet (about 5000 mg/kg body weight) for 110 days developed lesions of the forestomach (11). Propionic acid was given in the feed to dogs at 220, 735, or 2066 mg/kg/day (3000, 10000, and 30000 ppm) for 90 days. The high dose dogs showed reduced food consumption, increased incidence of epithelial hyperplasia in the esophagus, and increased nitrite in the urine. These effects were no longer present in dogs held for a 6 week recovery period (7). A limited study with calcium propionate in dogs for 90 days showed vomiting and diarrhea in animals fed 2523 mg/kg/day (43,500 ppm) (8).

Addition of sodium propionate to the diet of chicks and young rats accentuated the growth depression seen when their diet was deficient in vitamin B12 (11). Body weight gain in young lambs was not affected by 5600 mg/kg/day of sodium propionate in the diet for 50 days (11). When an adult male human was fed 6.0 g/day sodium propionate, the only effect noted was slightly alkaline urine (11).

c. Chronic, Reproduction and Teratology Studies

Twenty male rats per group were fed 0.4 or 4.0 percent propionic acid in the diet for 2 years. The high dose animals had hyperplasia and hyperplastic ulcers in the forestomach. (The rat forestomach has no counterpart in human anatomy).

Available data on calcium and sodium propionate indicate that:

1) Rats fed bread containing sodium propionate (about 4000 mg/kg/day) for a year showed no adverse effects, nor did rats fed a similar diet for 32 weeks, other than an initial depression of growth (11).

2) No maternal or fetal effects were seen upon feeding calcium propionate to pregnant animals at rates up to 300 mg/kg/day for rats and mice, or up to 400 mg/kg/day for hamsters and rabbits (9,11).

3) No teratogenicity was found in developing chick embryos when up to 100 mg/kg calcium propionate was injected into the yolk or air cell, although there was increased mortality at 5 and 10 mg/kg (11).

d. Mutagenicity

Propionic acid gave negative results in mutagenicity assays in 5 strains of S. typhimurium and one of S. cerevisiae, with and without activation (11).

Additional data on calcium and sodium propionate indicate that:

1) Calcium propionate tested in three strains of Salmonella typhimurium and one strain of Saccharomyces cerevisiae, with several activation systems, gave negative results. In host-mediated assay in mice, data for S. typhimurium strain G-46 found an increase in reversion frequency with calcium propionate that was unrelated to dose. Negative results with the calcium salt were found in cytogenic studies with bone marrow metaphase

chromosomes of rats, with anaphase chromosomes of humans, and in a dominant lethal assay in rats (11).

2) Sodium propionate showed higher incidences of abnormalities in developing chick embryos only at the highest level (10 mg/egg) by air cell administration, not in yolk treatment; however, 5 and 10 mg/egg levels had increased mortality. Sodium propionate also gave negative results in mutagenicity assays in 5 strains of S. typhimurium and one of S. cerevisiae, with and without activation (11).

e. Metabolism

Propionic acid is rapidly absorbed from the mammalian gastrointestinal tract (11). Propionic acid is a normal intermediary metabolite in the body. It is utilized by most organs and tissues, and can be metabolized to glucose, carbohydrates, amino acids, and lipids (9,11). It is produced in large quantities in ruminants. In nonruminants, propionic acid is one of the metabolic products from the breakdown of several amino acids. Propionic acid is formed in the oxidation of fatty acids and from the side chain of cholesterol (9).

2. Dietary Exposure

Since propionic acid is utilized by most organs and tissues, and is metabolized to glucose, carbohydrates, amino acids and lipids when ingested by livestock and poultry, residues in meat, milk or poultry are considered to be negligible. Propionic acid or mixtures of methylene bispropionate and oxy (bismethylene) bispropionate are exempt from the requirements of a tolerance when used as a post-harvest fungicide on alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut hay, peavine hay, rye grass, sorghum grain, soybean hay, sudan grass, timothy, vetch, and wheat grain (40 CFR 180.1023). Propionic acid is also exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c). Propionic acid is Generally Recognized As Safe (GRAS) (21 CFR 184.1081), by FDA for use in food.

Since no pesticide products currently contain calcium or sodium propionate as active ingredients, EPA intends to revoke tolerance exemptions established at 40 CFR 180.2(a) and 40 CFR

180.1015. The Agency also intends to establish for propionic acid exemptions from tolerances for meat, milk, poultry, and eggs as a result of application to livestock and poultry drinking water, poultry litter, and storage areas for silage and grain. The Agency has not yet determined whether it will require registrants to submit a petition for these exemptions or whether EPA will establish these exemptions on its own initiative. EPA will inform registrants of its decision in the near future.

3. Occupational Exposure

Propionic acid end-use products are formulated as concentrated liquids at 39.2% - 100% a.i. Propionic acid is used as a preservative and mold inhibitor fungicide for high moisture grain and animal feed as well as for other uses described in Section II. B. Propionic acid end-use products come in 51 - 55 gallon size drums. Products are sprayed on grain and forage with a low pressure spray system equipped with adequately arranged and calibrated nozzles to provide the desired spray coverage as grain is augured into storage bins. Application rates range from 1 - 4 gallons of 85% - 100% a.i., one gallon being used for every ton of grain, depending on the moisture content of grain or forage, and type and length of storage desired. Products are also applied to livestock and poultry drinking water and grain storage areas. Based on the use patterns, the potential exposure of applicators to propionic acid could be significant as well as to workers in the spray area. The potential for post-application exposure should be minimal (assuming the area is adequately ventilated). Certain protective clothing is appropriate for propionic acid users due to eye and skin hazards. The requirements are specified in Section V.C.2.

4. Human Risk Assessment

Several unusual factors about the case of propionic acid indicate that specific studies to fulfill all the standard data requirements are not necessary to regulate this substance as a pesticide. Propionic acid is a normal component of metabolism in the human body. Humans ordinarily consume propionic acid as a natural component of common foods and as an added ingredient. It is a natural component of butter and cheese, and may constitute as much as 1 percent of Swiss cheese. Dietary exposure from pesticidal use would be very low.

Other than eye and skin exposure, the human risks from occupational exposures are considered to be very low, because of the general knowledge of the chemical as well as its ongoing history of use by humans, including some pharmaceutical applications. However, eye and skin exposure does pose risks, i.e., the chemical is corrosive to the surface of the human eye and skin. Thus, adequate precautions must be taken to shield the eyes and prevent skin contact when the chemical is being handled. These precautions are detailed in the label statements required in Section V.C.2.

C. ENVIRONMENTAL ASSESSMENT

The Agency is not requiring any generic environmental fate data or ecological effects data on the active ingredient propionic acid considering the registered product formulations and uses. All data requirements for these disciplines that are specified in 40 CFR Part 158 are waived. The rationale for this decision is presented below in the "Environmental Fate Assessment" and the "Ecological Effects Assessment."

1. Environmental Fate Assessment

Under anaerobic conditions propionic acid acts as a carbon source for various microbes and is metabolized to acetic acid, methane, carbon dioxide and water (Lin et al, 1986). The only incident reports concerning propionic acid were detections in the tissue of the mussel (Mytilus edulis) (Yasuhara et al, 1986) and in ground water (Goerlitz et al, 1985) as the result of the break-down of petroleum pollution.

All environmental fate data requirements are waived for the currently registered uses based on the fact that propionic acid tends to be used as a carbon source by many microbes and is metabolized to carbon dioxide and water.

2. Ecological Effects Assessment

The Agency has reviewed the available ecotoxicity data base on file for propionic acid. A review of the studies in the data base indicate that propionic acid is no more than slightly toxic to birds, fish, aquatic invertebrates, and mammals.

As indicated above, review of registered uses of propionic acid indicates that all uses are either indoor treatments or limited outdoor uses for animal watering. On the basis of low toxicity and low potential for exposure, hazard to nontarget organisms is expected to be minimal.

Based on the above discussion, all ecological effects data requirements are waived for propionic acid.

3. Environmental Risk Assessment

The Agency does not anticipate significant risks associated with the specified use of propionic acid. No hazard or exposure issues have been identified that need to be addressed further. Therefore, no environmental fate or ecological effects data are required to support the reregistration of propionic acid.

IV. REREGISTRATION DECISION FOR PROPIONIC ACID

A. DETERMINATION OF ELIGIBILITY

Section 4(g)(2)(A) of FIFRA requires EPA to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The EPA has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing propionic acid as an active ingredient. It has also consulted and relied upon published literature as a source for technical information. The EPA has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing propionic acid. Appendix B identifies the generic data requirements that the EPA reviewed as part of its

determination of reregistration eligibility of propionic acid, and lists the submitted studies that the EPA found acceptable.

The data identified in Appendix B as well as information from the open literature are sufficient to allow the EPA to conduct a reasonable risk assessment for the registered uses of propionic acid The data available to the Agency supports the conclusion that the registered uses of propionic acid will not result in unreasonable adverse effects to the environment. The EPA has determined that all products containing propionic acid as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in section V of this document ("Product Reregistration").

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

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing propionic acid has been reviewed and determined to be substantially complete for reregistration.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPIONIC ACID

Labeling requirements for manufacturing-use products are the same as for end-use products of similar concentrations.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

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

B. PRODUCT SPECIFIC DATA REQUIREMENTS

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

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING PROPIONIC ACID

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

2. Products containing greater than 63% a.i. must include the following protective clothing label requirements: "Wear chemical-resistant gloves, chemical-resistant aprons, chemical-resistant footwear and goggles or face shield when loading application equipment unless a closed loading system is used. Avoid working near high concentrations of spray mist/vapor. Use with adequate ventilation. Wash thoroughly after handling."

3. In addition, end-use product labels which bear claims for uses on stored grain or hay must reflect the crop limitations as defined in 40 CFR 180.1023.

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION

FOR

PROPIONIC ACID

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR CASE #4078: PROPIONIC ACID, AND SALTS

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (ai)	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
active ingredient = **PROPIONIC ACID**									
FOOD USES									
ALFALFA									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
ANIMAL DRINKING WATER									
Water treatment; When needed; Equipment not on label	SC/L	8682 ppm	not spec	not spec	not spec	not spec	none	none	
BARLEY									
Stored commodity non-fumigation; When needed; Sprayer	RTU	31 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
BLUEGRASS									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
CLOVER									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
CORN, FIELD									
Stored commodity non-fumigation; When needed; Sprayer	RTU	31 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
COWPEAS									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (ai)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
							Allowed	Disallowed	
GRAIN/CEREAL/FLOUR STORAGE AREAS-EMPTY/FULL									
Indoor general surface treatment; timing not on label; equipment not on label	SC/L	0.29 lb ai/ 1000 sq ft of surface area	not spec	not spec	not spec	not spec	none	none	
GRASSES									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
LESPEDEZA									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
OATS									
Stored commodity non-fumigation; When needed; Sprayer	RTU	31 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
PEANUTS									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb ai/ton	not spec	not spec	not spec	not spec	none	none	
POULTRY									
Litter and bedding treatment; timing not on label; equipment not on label	SC/L	0.29 lb ai/ 1000 sq ft of litter	not spec	not spec	not spec	not spec	none	none	
POULTRY DRINKING WATER									
Water treatment; When needed; Equipment not on label	SC/L	8682 ppm	not spec	not spec	not spec	not spec	none	none	
SILOS									
Indoor general surface treatment; timing not on label; equipment not on label	SC/L	0.29 lb ai/ 1000 sq ft of surface area	not spec	not spec	not spec	not spec	none	none	

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (al)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitat'ons
							Allowed	Disallowed	
SUDANGRASS									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb al/ton	not spec	not spec	not spec	not spec	none	none	
TIMOTHY									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb al/ton	not spec	not spec	not spec	not spec	none	none	
VETCH									
Stored commodity non-fumigation; Postharvest; Sprayer	RTU	11.34 lb al/ton	not spec	not spec	not spec	not spec	none	none	
WHEAT									
Stored commodity non-fumigation; When needed; Sprayer	RTU	31 lb al/ton	not spec	not spec	not spec	not spec	none	none	

Abbreviations used

Header: max. = maximum; min. = minimum; apps. = applications; not spec. = not specified

Form: RTU = liquid ready to use; SC/L = soluble concentrate/liquid

Rate: al = active ingredient

APPENDIX B

Generic Data Requirements for Reregistration of Propionic Acid and Data Citations Supporting Reregistration

GUIDE TO APPENDIX B

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

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

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

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

2. Bibliographic citation (Column 2). If the EPA has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for Reregistration of Propionic Acid

Requirement		Propionic acid citation
61-1	Chemical Identity	(1)
63-2	Color	(1)
63-3	Physical State	(1)
63-4	Odor	(1)
63-5	Melting Point	(1)
63-6	Boiling Point	(1)
63-7	Density	(1)
63-8	Solubility	(1)
63-9	Vapor Pressure	(1)
63-10	Dissociation Constant	(1)
63-11	Octanol/Water Partition Coefficient	(1)
63-12	pH	(1)
63-13	Stability	(1)
171-4(a)	Nature of Residue - Plants	waived
171-4(b)	Nature of Residue - Animals	waived
171-4(c)	Residue Analytical Method - Plants	waived
171-4(d)	Residue Analytical Method - Animals	waived
171-4(e)	Storage Stability	waived
171-4(i)	Magnitude of Residue - Food Handling Establishments	waived
171-4(j)	Magnitude of Residue - Meat, Milk, Poultry, and Eggs	waived
171-4(l)	Processed Food	waived

(1) Information obtained from product chemistry information submitted with Phase III reregistration package in November 1990.

APPENDIX B - CONTINUED

Data Supporting Guideline Requirements for Reregistration of Propionic Acid

---

ECOLOGICAL EFFECTS

EPA waived 40 CFR Part 158 requirements as discussed in section III.

TOXICOLOGY

EPA waived 40 CFR Part 158 requirements for reasons discussed in section III.

ENVIRONMENTAL FATE

EPA waived 40 CFR Part 158 requirements for reasons discussed in section III.

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

APPENDIX C

PROPIONIC ACID BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting Reregistration

GUIDE TO APPENDIX C

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

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the EPA the EPA 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 EPA has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or MRID number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

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

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

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

c. Title. In some cases, it has been necessary for EPA 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 EPA in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

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

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

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

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn

followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

(1) 00068177 Union Carbide Corporation (1976) Acute Toxicity of Inert Ingredient 100% to the Bluegill Sunfish, "Lepomis macrochirus" Rafinesque and Rainbow Trout, "Salmo gairdneri" Richardson. Unpublished study. 9p.

(2) 00068178 Union Carbide Corporation (1976) Acute Toxicity of 100% Propionic Acid to the Water Flea, "Daphnia magna" Straus: AES Project No. 7619-500. Unpublished study. 9 p.

(3) 00079594 Fink, R. (1976) Final Report: Acute Oral LD50 - Mallard Duck: Project No. 142-106. (Unpublished study received July 16, 1977 under 10352-11; prepared by Truslow Farms, Inc., submitted by Union Carbide Corp., Chemicals and Plastics Operations Div., Tarrytown, NY; CDL:230871-B.

(4) 00079595 Fink, R. (1976) Final Report: Eight-day Dietary LC50 - Bobwhite Quail: Project No. 142-104. (Unpublished study received July 16, 1977 under 10352-11; prepared by Truslow Farms, Inc., submitted by Union Carbide Corp., Chemicals and Plastics Operations Div., Tarrytown, NY; CDL:230871-D.

(5) 00085932 Fink, R. (1976) Final Report: Acute Oral LD50 - Mallard Duck: Project No. 142-105. (Unpublished study received July 16, 1977 under 10352-11; prepared by Truslow Farms, Inc., submitted by Union Carbide Corp., Chemicals and Plastics Operations Div., Tarrytown, NY; CDL:230871-C.

(6) 00247883 Bioresearch Inc., (1982) Acute Inhalation of Propionic acid in the Rat and Acute Dermal LD50 of Propionic Acid in the Rabbit: Lab Project No. 82-3129A.

(7) 413389-01 BASF Aktiengesellschaft (1988) Three Month Dietary Study of the Toxicity of Propionic Acid in Beagle Dogs with a 6-week Recovery Period: Lab. Project No. 31D0473/8590. Unpublished study. 598 p.

(8) 413389-02 BASF Aktiengesellschaft (1989) Three Month Dietary Study of the Toxicity of Calcium Propionate in Beagle Dogs with a 6-week Recovery Period: Lab. Project No. 31D0449/87039. Unpublished study. 117 p.

The following are the sources of the references cited in this document:

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

(10) Eastman Chemical products, Material Safety Data Sheet-10, 591A-3 (05-85), 1975.

(11) FASEB (1979) Evaluation of the Health Aspects of Propionic Acid, Calcium Propionate, Sodium Propionate, Dilauryl Thiodipropionate, and Thiodipropionic Acid as Food Ingredients. NTIS PB80-104599.

(12) Goerlitz, D.F., Troutman, D.E., and Godsy, E.M. 1985. Migration of Wood Preserving Chemicals in Contaminated Groundwater in a Sand Aquifer at Pensacola, Florida. Environ. Sci. Tech. 19:955-61.

(13) Lin, C., Sato, K., Noike., and Matsumoto, J. 1986. Methanogenic Digestion Using Mixed Substrate of Acetic, Propionic and Butyric Acids. Water Res. 20:385-94.

(14) The Merck Index. Eleventh edition, (1989), p. 1127.

(15) Yasuhara, A. and Morita, M. 1987. Identification of Volatile Organic Components in Mussel Chemsphere 16:2559-65.