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United States Environmental Protection Agency
Office of Pesticide Programs
September 1991

EPA

Reregistration Eligibility Document (RED)

Sodium Diacetate

REREGISTRATION ELIGIBILITY DOCUMENT
SODIUM DIACETATE

LIST D

CASE 4001
ACETIC ACID

SEPTEMBER 1991

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

SODIUM DIACETATE REREGISTRATION ELIGIBILITY TEAM

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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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
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

The Environmental Protection Agency first registered a pesticide product containing sodium diacetate in 1968. Currently, sodium diacetate is registered in two end-use products as a fungicide and bactericide to prevent spoilage in post harvest feed crops. Both of the two registered products contain sodium diacetate as a single active ingredient.

The data base to support the reregistration of sodium diacetate is sufficient to allow the Agency to conduct reasonable risk assessments for these registered uses of sodium diacetate. These data support the Agency conclusion that the uses of sodium diacetate will not result in an unreasonable public health risk or unreasonable adverse effects to the environment. The Agency has conducted a tolerance risk assessment for sodium diacetate and our conclusions are discussed in Section III.B.2. Therefore, the Agency has determined that all products containing sodium diacetate as an active ingredient are eligible for reregistration.

Before reregistering each product, the Agency is requiring product specific data to be submitted within eight months of the issuance of this document. After reviewing these data and labels, the Agency will determine the reregistration eligibility of a product based on whether or not that product meets the requirements in section 3(c)(5) of the Act, that is, whether the product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to the environment. If these conditions are met, EPA will reregister the products.

Active ingredients subject to reregistration in this case included the chemical acetic acid. Since there are currently no products registered with acetic acid as an active ingredient, this document only addresses sodium diacetate.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the 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 sodium diacetate. The document consists of five sections. Section I is this introduction. Section II describes sodium diacetate, 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 sodium diacetate and Section V discusses product reregistration requirements. Additional details concerning the Agency's review of available data are available on request.[1]

The FIFRA list of active ingredients to be reregistered included acetic acid in this case. As there are no products currently registered with acetic acid as an active ingredient, the reregistration eligibility of acetic acid is not an issue. Acetic acid will be removed from the list of chemicals undergoing reregistration, and a complete data base to support a registration with acetic acid will be required by the Agency prior to the issuance of the registration or amendment.

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[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: Sodium diacetate

CAS Number: 126-96-5

Office of Pesticide Programs Chemical Code Number: 044008

Trade Name: Dykon

Empirical Formula: $CH_3COONaCH_3COOH$

B. USE PROFILE FOR SODIUM DIACETATE

Type of Pesticide: Fungicide, bactericide

Pests Controlled: Molds, including most post-harvest fungi and bacteria associated with soil, grasses, and terrestrial feed crops.

Registered Use Patterns and Sites: Terrestrial Feed Crops: Alfalfa (postharvest), clover (postharvest), field corn (postharvest), grasses (postharvest), oats (postharvest), sorghum (postharvest), and timothy (postharvest).

Formulation Types Registered: A 50% dust and a 100% soluble concentrate / solid formulation are registered.

Methods of Application:

The products are applied to the hay during the baling process, using a Gandy 902 JR applicator with the dust formulation or a pump spray with the soluble concentrate / solid formulation. The application rate is determined by the moisture content of the forage. Forage at 15 to 20 percent moisture is treated with 1.5 to 2 lbs. of the active ingredient per ton of forage. Forage with 20 to 25 percent moisture is treated with 2.5 lbs. of the active ingredient per ton of forage, the maximum permitted rate.

The products are applied to silage as an "aid" in fermentation, to preserve corn, hay, sorghum, oats, and grass stored in conventional upright, oxygen limiting, pit and bunker silos. The

products are applied at the time of chopping or at the blower when silage is being loaded into the silo using a Gandy 902 JR applicator with the dust formulation or a liquid applicator with the soluble concentrate / solid. Corn, hay, grass, oats, and sorghum silage at 50 to 70 percent moisture content is treated with the products at 0.5 to 1 lb. active ingredient per ton of silage; for high moisture ensiled corn at 25 to 35 percent moisture, the recommended application rate is 1 to 2 lbs. of the dust or 2 to 3 lbs. of the soluble concentrate / solid formulation per ton of ensiled corn.

Limitations: Do not use these products on hay with more than 25 percent moisture content, on silage with less than 50 or more than 70 percent moisture content, or on high-moisture ensiled corn with less than 25 or more than 35 percent moisture content. With treated hay, bales should be stacked to maximize ventilation. Hay is to be fed to livestock and poultry only. Untreated hay must not be stored on treated hay while curing out. Water must not be contaminated by cleaning of equipment or disposal of wastes.

C. REGULATORY HISTORY

In 1968 the Agency first registered a pesticide product with sodium diacetate as an active ingredient in a dust formulation, as a food preservative to control molds and rope-forming bacteria in breads and cake. Later registrations were issued for products used on livestock feed crops to preserve the quality of the feed.

An exemption from tolerance was issued by the Agency on May 15, 1981 (40 CFR 180.1058), based on the status of the chemical as Generally Recognized as Safe (GRAS) (21 CFR 184.1754), for the uses of sodium diacetate as a post-harvest application fungicide to the following feeds: alfalfa hay, barley grain, Bermuda grass hay, blue grass hay, brome grass hay, clover hay, corn grain, cowpea hay, fescue hay, lespedeza hay, lupines, oat grain, orchard grass hay, peanut hay, peavine hay, rye grass hay, sorghum grain, soybean hay, sudan grass hay, timothy hay, vetch hay, and wheat grain. This exemption is still appropriate.

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

The EPA has conducted a thorough review of the scientific data base for sodium diacetate. Based on the evaluation of these data, the EPA has no reason to request additional data, except as confirmatory information.

A. DESCRIPTION OF ACTIVE INGREDIENT AND ASSESSMENT OF PRODUCT CHEMISTRY

Sodium diacetate is a white crystalline solid at room temperature with a slightly pungent odor. It decomposes above 150°C and is hygroscopic. It is described as a "bound" compound of sodium acetate and acetic acid. It is soluble in water, liberating acetic acid. It is slightly soluble in alcohol and is insoluble in ether (5).

Certain chemistry data to support sodium diacetate for reregistration are not currently available to the Agency. The studies are being called in under the product-specific data call-in for the product labeled as 100 % sodium diacetate. The studies required are as follows:

Guideline number	name
61-1	Chemical Identity
61-2(a)	Beginning materials and Manufacturing Process
61-2(b)	Discussion of Impurities
62-1	Preliminary Analysis
62-2	Certification of Limits
62-3	Analytical Method
63-7	Density
63-9	Vapor Pressure
63-10	Dissociation Constant
63-11	Octanol/Water Partition Coefficient
63-12	pH
63-13	Stability

The Agency believes that the large body of information in the public literature describing sodium diacetate is adequate. The potential impurities which may be introduced in manufacture of the chemical are also of little concern. The additional data required from the registrant are confirmatory in nature.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology

The Agency is relying on information from published scientific sources. For the data base EPA is using data on acetic acid and acetates in addition to data on sodium diacetate. EPA concludes that this collection of data from different sources and on different but related chemical compounds is appropriate and sufficient for EPA to conduct an adequate toxicological assessment of the pesticidal use of sodium diacetate. EPA concludes no additional toxicity data on sodium diacetate are necessary.

Sodium diacetate is a hydrated molecular complex of acetic acid and sodium acetate which dissociates to acetate, sodium, and hydrogen ions, and information on the toxicity of acetates and acetic acid is relevant in determining the safety of sodium diacetate. In addition, the ions produced by the dissociation of the sodium diacetate molecule are normal components of plants and animals, and of human foods. Acetates are normal metabolic intermediates in living organisms and are formed during the metabolism of food substances. Acetates and acetic acid have long been used safely and without major adverse effects in both human and animal foods at moderate levels of consumption (3). There is a substantial volume of information on acetates and acetic acid in the literature which covers major biological considerations, and the safety of sodium diacetate can be based upon the information about the safety of acetates in general. Thus, there is no reason to expect adverse effects from the reasonable pesticide use of sodium diacetate. The discussions which follow will include information based on acetic acid as well as sodium diacetate.

The Food and Drug Administration, in 21 CFR 184.1754, lists sodium diacetate as a substance generally recognized as safe (GRAS) for use in food as an antimicrobial agent, flavoring agent, and pH control agent. That Agency for use as a sequestrant for animal feed (21 CFR 582.6754).

The Food and Drug Administration, in 21 CFR 184.1005, lists acetic acid as a substance generally recognized as safe (GRAS) for use in food. The listing includes uses for curing and pickling, flavoring, pH control, solvent, vehicle, and boiler water additive, with use levels of up to 9.0 percent acetic acid in condiments and relishes.

a. Acute Toxicity

Acetic acid has toxic effects on the central nervous system and kidneys. Inhaled acetic acid vapor is irritating to the upper respiratory tract (1).

Based on acute toxicity studies with sodium diacetate, the Agency classifies sodium diacetate as Tox category IV for oral and dermal toxicity. The oral LD_{50} in rats is 5,600 mg/kg. The dermal LD_{50} in rats is greater than 2,000 mg/kg. In an acute rat inhalation study of 8 hours duration, the only finding was some evidence of slight petechial hemorrhage in the lungs; an LC_{50} was not determined. Sodium diacetate is an eye irritant with category II toxicity. An eye irritation study in rabbits found chemosis and redness which, in some animals, persisted through the seventh day. Another eye irritation study in rabbits found severe corneal necrosis with a 15 percent solution but only trace injuries with a 5 percent solution. A primary dermal irritation study in rabbits found no irritation with a 50 percent solution, a Tox. category IV classification.

TOXICITY ROUTE	VALUE	CATEGORY
ACUTE ORAL	5600 MG/KG	IV
ACUTE DERMAL	> 2000 MG/KG	IV
ACUTE INHALATION	NOT DETERMINED	****
EYE IRRITATION	CORNEAL INVOLVEMENT CLEARING IN 8 - 21 DAYS	II
DERMAL IRRITATION	NO IRRITATION	IV
SKIN SENSITIZER	NOT DETERMINED	****

b. Subchronic Toxicity

Workers exposed to acetic acid through the inhalation route may tolerate concentrations up to 30 ppm without severe injury if acclimatized. Subchronic studies conducted in various animal species and with differing dosing regimes of acetic acid are reported in the science literature. In one subchronic inhalation study, male rats exposed for 95 days to 0.01, 0.2, or 5.0 mg/m^3 acetic acid vapor in air developed progressive muscle imbalance, increases of blood cholinesterase activity and serum globulins, and decreases of serum albumins in the two higher doses. The highest dose group also had raised white blood cell counts and decreases in ascorbic acid levels (6).

An 8 week feeding study with rats fed 2 percent sodium diacetate in the diet found no effects and concluded that the NOEL was greater than 1,000 mg/kg body weight.

In a subchronic study four groups of three to six rats were given 0.01, 0.1, 0.25, or 0.5 percent acetic acid in drinking water (up to 390 mg/kg body weight) for periods of nine to 15 weeks. Fluid intake was the same in all groups. Rats at the 0.5 percent level experienced immediate, progressive reduction in body weight gain, loss of appetite, and up to a 27 percent reduction in food consumption. Mortality was unaffected. None of these effects were seen at the lower doses (2, 3).

In another experiment, groups of three to four rats survived for 14 days when given 1800 mg/kg body weight per day of free acid intragastrically or 4200 - 4800 mg/kg body weight of sodium acetate, but survived only three to five days on daily intra-gastric doses of 2400 mg/kg body weight of free acid. Animals lost weight and showed blistered paws and reddened noses before death at fourteen days. No autopsies were done (4).

Four groups of two young pigs each were fed daily diets containing 0, 240, 720, 960, or 1200 mg/kg body weight per day for successive 30-day periods to a total of 150 days. There were no significant differences in growth rate, weight gain, early morning urinary ammonia, and terminal blood pH between controls and test groups. No autopsies were done (2).

c. Other Toxicological Effects

Teratologic testing of apple cider vinegar containing 5 percent acetic acid was done in pregnant rabbits, mice, and rats at up to 1,600 mg/kg body weight daily. These tests did not show any maternal or fetal effects. In another study, there were no teratogenic effects seen in developing chicken embryos in which up to 200 mg of sodium acetate / kg of egg was injected into the egg's air cell or yolk. However, there was an LD_{50} of 91.5 mg/kg when injected into the yolk of unincubated eggs (3).

Different mutagenicity testing with sodium acetate or acetic acid has generally not shown positive results.

Female rabbits given doses of 0.1 to 0.2 g/kg body weight of acetic acid twice a day orally for five months or 0.1 to 0.7 g/kg body weight of acetic acid in drinking water for 13 months did not express tumors. Male rats given oral doses of 350 mg/kg body weight of sodium acetate three times weekly for 63 days, then 140 mg/kg body weight three times

weekly for 72 days showed no signs of tumors after 135 days (3).

d. Metabolism

Acetic acid is absorbed readily from the gastrointestinal tract and from the lungs (FASEB, Clayton). It is also incorporated naturally and readily into intermediary metabolism by most tissues of the body and is thus utilized rapidly (1).

Acetate is completely utilized in oxidative metabolism or in anabolic syntheses. Isotope experiments have shown acetate to be utilized in the formation of glycogen, carbohydrate intermediates, phospholipids, and fatty acids, as well as in cholesterol and steroid synthesis (1, 3, 4). In addition, it participates in the acetylation of amines and may be converted to alanine by transamination and thence incorporated into proteins of plasma, liver, kidney, gut mucosa, muscle, and brain (4). It has been estimated that the rat forms acetate at the rate of one percent of its body weight per day (3).

2. Dietary Exposure and Tolerance Assessment

Since acetic acid is completely utilized in metabolism in the formation of glycogen, carbohydrate intermediates, phospholipids, and fatty acids, as well as in cholesterol and steroid synthesis, the residues in meat, milk, or poultry are considered to be negligible. Acetic acid and sodium diacetate are exempt from the requirement of a tolerance when used post-harvest 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 180.1029 and 180.1058). Acetic 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). Both acetic acid and sodium diacetate are considered by the Food and Drug Administration to be Generally Recognized as Safe (GRAS) (21 CFR 184.1005 and 184.1754) for use in food.

Since no pesticide products currently contain acetic acid as an active ingredient, EPA intends to revoke the exemption from tolerances established at 40 CFR 180.1029.

EPA also intends to revoke exemptions from tolerances for crops not registered for sodium diacetate. This will include the exemptions from tolerances established at 40 CFR

180.1058 for the following postharvest applications: barley grain, cowpea hay, fescue hay, lespedeza hay, lupines, peanut hay, peavine hay, soybean hay, vetch hay, and wheat grain. These uses are not listed on product labelling for sodium diacetate.

3. Occupational Exposure

Mixer and loader workers may experience significant exposure during the mixing and loading of the soluble powder for liquid application. Likewise, for the dust formulation, the potential for significant worker exposure exists via the dermal and inhalation routes during mixing and loading. If conducted in a closed system, the potential for exposure during mixing / loading would be minimized. Exposure to applicators should be minimal, based on the application with mechanical applicators.

When used in accordance with the product label directions and precautions, EPA believes such exposure would vary depending on whether the products are applied to conventional square bales or to round stacks of hay. Activities involving square bales may require more human contact since they are more portable and more likely to be moved by hand than the larger round bales.

While EPA lacks worker exposure data specific to sodium diacetate and its registered uses, it believes that these uses could provide varying degrees of dermal, inhalation, and eye exposure during mixing, loading, and application of the pesticide products and the handling of treated bales of hay.

Exposure can result from application of both the dust and liquid spray products. Current product labels do not direct workers to wear protective clothing or equipment such as gloves, long sleeves and pants, or goggles. However, EPA does not believe there is a need to acquire exposure data on sodium diacetate in order to conduct a detailed exposure assessment because of the low acute toxicity, except for eye irritation, and the absence of significant sub-chronic and chronic toxicity.

As described above, sodium diacetate is applied to various livestock feedstuffs for preservative value. EPA has exempted sodium diacetate from the requirement of tolerances on these items on the basis of their being Generally Recognized as Safe (GRAS). EPA believes any exposure to sodium diacetate, its degradates sodium acetate and acetate, metabolic by-products through the consumption of meat, milk, poultry, and eggs from livestock fed treated feed is inconsequential.

4. Human Risk Assessment

As discussed above in the occupational and dietary exposure assessments, EPA concludes the exposure to humans from proper application of sodium diacetate to livestock feed items raises a concern for eye hazards to workers and is otherwise inconsequential for the general public consuming meat, milk, poultry, and eggs. In order to mitigate the potential for exposure to the eyes during handling and application of the products, EPA is requiring through this document the use of protective equipment. The specific requirements are provided in Section V.C., Product Reregistration Labeling Requirements.

EPA has also briefly discussed above sodium diacetate's chemistry relative to sodium acetate and acetate as well as chemical and metabolic properties of these individual compounds. Given these compounds' low toxicities, natural occurrence, and inherent functions in the metabolic pathways of humans and domestic animals EPA is not concerned about the negligible human dietary exposure or risk from the use of sodium diacetate. The Agency is therefore not requiring any human health studies for sodium diacetate.

C. ENVIRONMENTAL ASSESSMENT

EPA is relying on general knowledge about sodium diacetate's use pattern, its chemistry and toxicity on which to base its environmental assessments. No generic data on this active ingredient is required. EPA believes it has sufficient information on sodium diacetate to assess the possible effects of this pesticide active ingredient on the environment.

1. Environmental Fate Assessment

Applications of sodium diacetate to post-harvest livestock feed crops are primarily within farm facilities so there is limited environmental exposure.

Exposure to aquatic environments from runoff will only result in short-term pH changes that will be counteracted by the natural buffering capacity of the water.

There is sufficient knowledge about sodium diacetate to make an assessment that the compound's impact on the environment will be negligible.

2. Ecological Effects Assessment

Sodium diacetate is applied to post-harvest

terrestrial feed crops primarily inside farm facilities, presenting little potential for exposure to non-target organisms. In addition, because sodium diacetate and its degradates have low toxicity and are normally present and function in metabolic pathways of animals, the risk to wildlife is minimal.

3. Environmental Risk Assessment

The Agency does not foresee the potential for significant risks associated with the specified use of sodium diacetate. 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 sodium diacetate.

IV. REREGISTRATION DECISION FOR SODIUM DIACETATE

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. As no products are currently registered with acetic acid as an active ingredient and the chemical is not supported for reregistration, the Agency will require submission of a complete study data base for registration applications which include acetic acid as an active ingredient prior to the issuance of the registration or amendment. For products containing sodium diacetate as an active ingredient, the EPA has waived the requirement of the submission of the generic (i.e., active ingredient specific) data except for product chemistry to support reregistration. Rather, it has consulted and relied upon published literature as a source for technical information. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing sodium diacetate. Appendix B identifies the generic data requirements that the EPA reviewed as part of its determination of reregistration eligibility of sodium diacetate and lists the submitted studies that the Agency 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 sodium diacetate. The data available to the EPA supports the conclusion that the registered uses of sodium diacetate will not result in unreasonable adverse effects to humans or the environment. The EPA has

determined that all products containing sodium diacetate 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 data identified in Appendix B, the current guidelines for conducting acceptable studies to generate such data, and the published literature. Although the EPA has found that products containing sodium diacetate 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 sodium diacetate 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 sodium diacetate has been reviewed and determined to be complete for reregistration.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM DIACETATE

There are no manufacturing-use products registered with sodium diacetate as an active ingredient.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredient, sodium diacetate, 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 SODIUM DIACETATE

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.

To address the classification of sodium diacetate as Toxicity Category II for eye irritation, the following statement must be included:

" Causes eye irritation. Do not get in eyes. Wear goggles or a face shield during use."

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION FOR SODIUM DIACETATE

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR CASE #4001: ACETIC 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 = **SODIUM DIACETATE**									
FOOD/FEED USES									
ALFALFA (FORAGE/FODDER/STRAW/HAY-NON GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry
Spray; Postharvest; Equipment not on label	SC/L	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry
CLOVER (FORAGE/FODDER/STRAW/HAY-NON GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry
Spray; Postharvest; Equipment not on label	SC/L	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry
CORN (FORAGE/FODDER/HAY-GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	2 lb ai/ton	not spec	not spec	not spec	not spec	none	none	silage moisture must be < 70%; high moisture ensiled corn must be < 35%
Spray; Postharvest; Equipment not on label	SC/L	3 lb ai/ton	not spec	not spec	not spec	not spec	none	none	silage moisture must be < 70%; high moisture ensiled corn must be < 35%
GRASSES (FORAGE/FODDER/HAY-GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
Spray; Postharvest; Equipment not on label	SC/L	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%

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	
OATS (FORAGE/FODDER/HAY-GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	1 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
Spray; Postharvest; Equipment not on label	SC/L	1 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
SORGHUM (FORAGE/FODDER/HAY-GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	1 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
Spray; Postharvest; Equipment not on label	SC/L	1 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
TIMOTHY (FORAGE/FODDER/HAY-GRASS)									
Stored commodity non-fumigation; Postharvest; Equipment not on label	not spec/S	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%
Spray; Postharvest; Equipment not on label	SC/L	2.5 lb ai/ton	not spec	not spec	not spec	not spec	none	none	hay moisture must be < 25%; treated hay may only be fed to livestock or poultry; silage moisture must be < 70%

Abbreviations used

Header: max. = maximum; min. = minimum; apps. = applications; not spec. = not specified; NA = not applicable
Form: not spec/S = form not specified/solid; SC/L = soluble concentrate/solid
Rate: ai = active ingredient

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM DIACETATE 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. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. 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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Any other designations will be defined in a footnote to the table.

3. Bibliographic citation (Column 3). If the EPA has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF SODIUM DIACETATE

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
PRODUCT CHEMISTRY			
61-1	Chemical Identity	B	data required
61-2(a)	Beginning Materials and Manufacturing Process	B	data required
61-2(b)	Discussion of Impurities	B	data required
62-1	Preliminary Analysis	B	data required
62-2	Certification of Limits	B	data required
62-3	Analytical Method	B	data required
63-7	Density	B	data required
63-9	Vapor Pressure	B	data required
63-10	Dissociation Constant	B	data required
63-11	Octanol/Water Partition Coefficient	B	data required
63-12	pH	B	data required
63-13	Stability	B	data required

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF SODIUM DIACETATE

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
171-4(a)	Nature of Residue Plants	B	waived
171-4(b)	Nature of Residue Animals	B	waived
171-4(c)	Residue Analytical Method Plants	B	waived
171-4(d)	Residue Analytical Method Animals	B	waived
171-4(e)	Storage Stability	B	waived
171-4(i)	Magnitude of Residue Food Handling Establishments	B	waived
171-4(j)	Magnitude of Residue Meat, Milk, Poultry, Eggs	B	waived
171-4(l)	Processed Food	B	waived

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF SODIUM DIACETATE

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION

TOXICOLOGY

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

ECOLOGICAL EFFECTS

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

ENVIRONMENTAL FATE

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

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

APPENDIX C

BIBLIOGRAPHIC CITATIONS FOR SODIUM DIACETATE

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, t 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

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

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

(2) FAO/WHO Techn. Rep. Ser. No. 539, 1974.

(3) FASEB, 1977. "Evaluation of the Health Aspects of Acetic Acid, Sodium Acetate, and Sodium Diacetate as Food Ingredients". NTIS PB-274 670.

(4) J.R. Geigy S.A. (1970) Documenta, Geigy, 7th ed. Basle; as cited in FAO/WHO World Health Org. Techn. Rep. Ser. No. 539, 1974.

(5) The Merck Index. Tenth edition, (1983), p. 1234.

(6) Tracor-Jitco, Inc. (1974) Scientific Literature Reviews on Generally Recognized as Safe (GRAS) Food Ingredients, Acetic Acid and Acetates. Prepared for FDA. NTIS PB-234 898.

APPENDIX D

PRODUCT DATA CALL-IN

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4001 Acetic acid, and salts EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	PRODUCT CHEMISTRY - REGULAR CHEMICAL								
61-1	Product Identity & Compos (1)					ALL	MP/EP	8 mos.	
61-2(a)	Begin. mat. & mnfg. proc (1,2)					ALL	MP/EP	8 mos.	
61-2(b)	Discussion of Impurities (1,3)					ALL	MP/EP	8 mos.	
62-1	Preliminary Analysis (1,4)					ALL	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ALL	MP/EP	8 mos.	
62-3	Analytical Method (1)					ALL	MP/EP	8 mos.	
63-2	Color					ALL	MP/EP	8 mos.	
63-3	Physical State					ALL	MP/EP	8 mos.	
63-4	Odor					ALL	MP/EP	8 mos.	
63-5	Melting Point (6)					ALL	MP/EP	8 mos.	
63-6	Boiling Point (7)					ALL	MP/EP	8 mos.	
63-7	Density					ALL	MP/EP	8 mos.	
63-8	Solubility					ALL	MP/EP	8 mos.	
63-9	Vapor Pressure					ALL	MP/EP	8 mos.	
63-10	Dissociation Constant					ALL	MP/EP	8 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4001 Acetic acid, and salts EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-11	Oct/Water partition Coef.(8)					ALL	MP/EP	8 mos.	
63-12	pH (9)					ALL	MP/EP	8 mos.	
63-13	Stability					ALL	MP/EP	8 mos.	
63-14	Oxidizing/Reducing Action(10)					ALL	MP/EP	8 mos.	
63-15	Flammability (11)					ALL	MP/EP	8 mos.	
63-16	Explodability (12)					ALL	MP/EP	8 mos.	
63-17	Storage stability					ALL	MP/EP	8 mos.	
63-18	Viscosity (13)					ALL	MP/EP	8 mos.	
63-19	Miscibility (14)					ALL	MP/EP	8 mos.	
63-20	Corrosion characteristics					ALL	MP/EP	8 mos.	
63-21	Dielectric breakdown volt(15)					ALL	MP/EP	8 mos.	
64-1	Submittal of samples (16)					ALL	MP/EP	8 mos.	
	ACUTE TOXICITY - REGULAR CHEMICAL								
81-1	Acute oral tox. rat (1,5,6)					ALL	MP/EP	8 mos.	
81-2	Acute dermal tox. rabbit/rat (1,2,6)					ALL	MP/EP	8 mos.	
81-3	Acute inhal. tox rat (3)					ALL	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ALL	MP/EP	8 mos.	
81-5	Primary dermal irritation(1,2)					ALL	MP/EP	8 mos.	

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

Date

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4001 Acetic acid, and salts EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
81-6	Dermal sensitization (4)					ALL	MP/EP	8 MOS.	

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

Date

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

FOOTNOTES FOR GUIDELINE REQUIREMENTS

The following notes are referenced in column two (5. Study Title) of the Requirements Status and registrant's Reponse form

Case # and Name: 4001 Acetic acid, and salts

PRODUCT CHEMISTRY - REGULAR CHEMICAL

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
6 Required if technical chemical is solid at room temperature.
7 Required if technical chemical is liquid at room temperature.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
16 Basic manufactures are required to provide the Agency with a sample of each TGAI used to formulate a product when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis. Material safety data sheets should accompany samples as specified by OSHA in 29 CFR 1910.1200.

ACUTE TOXICITY - REGULAR CHEMICAL

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
5 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
6 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

FOOTNOTES FOR GUIDELINE REQUIREMENTS

The following notes are referenced in column two (5. Study Title) of the Requirements Status and registrant's Reponse form

Case # and Name: 4001 Acetic acid, and salts