United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-95-025
September 1995

Reregistration Eligibility Decision (RED)

Sodium Fluoroacetate

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical sodium fluoroacetate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product's use, and its decisions and conditions under which this use and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Frank Rubis at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Leonard Ryan at (703) 308-8067.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified

limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

SODIUM FLUOROACETATE

LIST C

CASE 3073

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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SODIUM FLUOROACETATE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal use of sodium fluoroacetate in the United States. Based on its review of the targe database, the Agency has determined that the currently registered uses will not cause unreasonable risk to humans or the environment and that these uses are therefore is eligible for reregistration.

Sodium fluoroacetate (Compound 1080) is an acute toxicant predacide against coyotes which prey on sheep and goats. Currently registered end-use products are 1% solutions which are injected into the rubber reservoirs of Livestock Protection Collars. These collars are strapped to the throats of sheep or goats. Coyotes attempting to kill collared livestock are likely to puncture the collars and to be fatally poisoned by sodium fluoroacetate as a result.

Sodium fluoroacetate is highly toxic to warm blooded animals, including humans, when taken internally. Additionally, sodium fluoroacetate may pose a high acute risk to non-target birds and mammals that may scavenge the carcasses of predators that are killed from biting the collared livestock. State-limited registrations for sodium fluoroacetate collars have been issued in Texas, New Mexico, Wyoming, Montana, and South Dakota. The use of these products are further limited to only those states which have an EPA-approved certification and training program, which currently includes only Texas, New Mexico, Wyoming, and Montana. The use is further restricted within these four states to specific counties when there is potential for adverse effects to endangered species.

Before reregistering the products containing sodium fluoroacetate, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a 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 identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" 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 eligibility of the registered uses of sodium fluoroacetate. The document consists of six sections. Section I is the introduction. Section II describes sodium fluoroacetate, 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 presents the reregistration decision for sodium fluoroacetate. Section V discusses the reregistration requirements for sodium fluoroacetate Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Sodium Fluoroacetate
- **Chemical Name:** Sodium Monofluoroacetate
- **Chemical Family:** Fluoroacetic Acid
- **CAS Registry Number:** 62-74-8
- **OPP Chemical Code:** 075003
- **Empirical Formula:** F-CH_2-C-O_2-Na
- **Trade and Other Names:** Compound 1080
- **Basic Manufacturer:** U. S. Department of Agriculture-registrant
  Tull Chemical Company, Oxford. AL.-manufacturer

B. Use Profile

Presented below is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the registered uses of sodium fluoroacetate is in Appendix A.

For **Sodium Fluoroacetate**:

Type of Pesticide: Predacide

Mode of action: Stomach poison.

Use Sites:	Sheep, lambs, kids, goats, dairy goats (lactating or unspecified), goats (wool/angora animal)
Target Pests:	Product kills coyotes preying on sheep or goats.
Formulation Types	Formulation Intermediate - 90% a.i.
Registered:	Collar: 1% a.i. available. All Collars contain 1.1 oz of formulated material which is equal to approximately .00067 lbs a.i./collar.
Method and Rates of Application:	When predation is anticipated, collars (one collar per collared animal) are strapped in place with the rubber toxicant reservoirs positioned in the throat regions of sheep or goats in target flocks or herds. The sodium fluoroacetate solution is released if a collar reservoir is punctured by an attacking coyote or by another agent. Up to 20 collars may be used in fenced pastures up to 100 acres in size. Up to 50 collars may be used in pastures of 101 to 640 acres. Up to 100 collars may be used in pastures of 641 to 10,000 acres.
Use Practice Limitations:	For a complete listing of product limitations, see Section V, Labeling Requirements for End-use Products.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of sodium fluoroacetate. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Table 1, below, summarizes the amounts of sodium fluoroacetate used by site.

Table 1. Estimates of Typical Usage of Sodium Fluoroacetate

Site	Head Available (000)	Head Treated (000)	Site Treated (%)	Lbs a.i. applied
Sheep - US	9080- 10850	0.6 - 0.7	< 0.01	< 1
MT only	520 - 580	-	-	-
NM only	460 - 510	-	-	-
SD only	540 - 590	-	-	-
TX only	1710 - 1940	-	-	-
WY only	830 - 850	-	-	-
Goats - US	2250 - 2550	0.2	< 0.01	< 0.5
NM only	80-90	-	-	-
TX only	1650 - 1960	-	-	-
Total - US	11330 - 13400	0.8 - 0.9	< 0.01	< 1

1987 Census of Agriculture: US
Pesticide Use in Wyoming, 1990
Wyoming Agricultural Statistics, 1992
New Mexico Agricultural Statistics, 1988
South Dakota Agriculture on the Move, 1993-1994
Texas Ag. Facts, Annual Summary, 2/25/94Montana Agricultural Statistics, 1987

USDA/APHIS Animal Damage Control
EPA information, reports and proprietary sources

Notes: Coyote is the only active pest. Goats and sheep are the only active sites. Method of application is by collar.

D. Data Requirements

The data required to support the uses of sodium fluoroacetate are identified in Appendix B. This includes all data requirements identified by the Agency to support reregistration for currently registered use.

E. Regulatory History

Origins and Early Development

This chemical case pertains to a large "family" of chemicals which are metabolized in the manner of fluoroacetic acid and which, consequently, are very toxic (Pattison, 1959). Of these chemicals, sodium monofluoroacetate (Compound 1080) and fluoroacetamide (Compound 1081) have been registered as pesticides in the U.S. For reasons outlined below, there no longer are any registered uses of fluoroacetamide in the U.S. Legal use of sodium monofluoroacetate is limited to livestock protection collar products.

Poisons in the fluoroacetic acid "family" occur naturally in Western Australian and South African plants that have been implicated in the poisoning of livestock (Aplin, 1979; Pattison, 1959). The gifblaar plant (Dichapetalum cymosum) of South Africa arises as

small tufts of leaves and flowers from long and extensively branched underground stems. Africans have used extracts of gifblaar (which means "toxic leaf") and related plants as arrow poisons.

The active substance in gifblaar was extracted as its potassium salt, potassium fluoroacetate, in 1943 or 1944 (Marais, 1944 cited by Pattison, 1959). By that time, research already had been undertaken on synthesized fluoroacetic acid and related compounds.

Synthesis of fluoroacetic acid was reported in 1896 by the Belgian researcher Swarts (cited by Pattison, 1959). Fluoroacetic acid was patented in Germany in 1930 as a mothproofing agent. Subsequently, Germans researched a number of related compounds as potential chemical warfare agents and systemic insecticides. In the mid-to-late 1930s, Polish military researchers discovered that fluoroacetate compounds are extremely toxic materials. Much of the research conducted in Nazi-occupied countries prior to the end of World War II was either lost or very late in being reported publicly. The escape of a Polish scientist to England brought elements of the knowledge gained in Poland to the allied side.

Further research took place in England and in the U.S. English scientists ultimately concluded that "compounds that form fluoroacetic acid by hydrolysis and/or oxidation are toxic." (Pattison, 1959, p. 19)

In the U.S., research on compounds related to fluoroacetic acid led to several developments, including the development of sodium fluoroacetate as a rodenticide and mammalian predacide and fluoroacetamide as a rodenticide. The names 1080 and 1081 for sodium fluoroacetate and fluoroacetamide, respectively, came from the invoice numbers that these materials were assigned in U.S. Government laboratories (Peacock, 1964).

Extensive research on this family of chemicals after World War II led to a general understanding of the mode of toxic action and the development of analytical methods which, if not extremely sensitive by present standards, were at least able to detect the use of compounds related to fluoroacetic acid in certain homicides (Pattison, 1959). However, the problem of poor recovery of sodium fluoroacetate in or on animal tissues remained until the mid 1980s (Kimball and Mishelanie, 1993).

U.S. Regulatory History of Sodium Fluoroacetate

Development and use of sodium fluoroacetate as a predacide and rodenticide in the U.S. began in the 1940s (e.g., Robinson, 1948), prior to the 1947 enactment of the Federal Insecticide, Fungicide and Rodenticide Act (1947) by which requirements for Federal registration of pesticide products were instituted. Products containing sodium fluoroacetate were among those registered shortly after the registration requirement went

into effect. Pattison (1959) reports that the Monsanto Corporation produced about 5 tons of sodium fluoroacetate in 1948. In 1955, Monsanto's 90% sodium fluoroacetate product was transferred to Tull Chemical Company of Oxford, AL. By the early 1970s, Tull Chemical Company was the only firm legally producing sodium fluoroacetate for pest control purposes in the U.S. Tull's registered product at the time, EPA Registration No. 5217-1, was a 90% sodium fluoroacetate concentrate which was labeled for mixing baits that could be applied to control a variety of rodents and predatory mammals.

In 1964 and again in 1971, the use of poisons to control predatory mammals were reviewed by select committees (Leopold, et al 1964; Cain, et al, 1972). Following the issuance of the "Cain Report", President Nixon issued Executive Order 11643, which banned the use of poisons to control predators on Federal lands. Shortly thereafter, EPA issued PR Notice 72-2 which canceled all registered predator control uses of sodium fluoroacetate, sodium cyanide, and strychnine (Ruckelshaus, 1972). Subsequent to the cancellation of predacidal uses of sodium fluoroacetate, several parties sought to have such uses restored.

There was a period of illegal use of sodium fluoroacetate as a predacide in Wyoming from 1975 to 1977 (Thomas, 1983, p. 22; see also Nissen, 1982, p. 79; and Johnson, 1978).

In 1977, the U.S. Department of the Interior (USDI) applied for an Experimental Use Permit (EUP) to investigate the potential risks and benefits associated with the use of sodium fluoroacetate in "toxic collars" which would be placed on the necks of sheep and goats. Rubber pouches containing sodium fluoroacetate solution would be positioned around the animals' throat regions where they would be likely to be ruptured by the teeth of coyotes that attempted to kill the livestock with species-typical throat bites.

In 1981, EPA was petitioned by the USDI and livestock interests to revisit the 1972 predacide cancellation decision with respect to sodium fluoroacetate. EPA responded by holding informal hearings on the issue in 1981 and formal, Subpart D administrative hearings in 1982. The Subpart D hearings considered reinstatement of sodium fluoroacetate in injected-carcass bait stations and three additional types of applications: toxic collars, small "single-dose baits" intended to provide enough toxicant to reliably kill one coyote, and "smear posts." The initial and final decisions (Nissen, 1982; Thomas, 1983) permitted EPA to consider applications for registration of sodium fluoroacetate in toxic collars and single-dose baits and rejected the carcass baits and smear posts.

On July 18, 1985, EPA granted a registration to USDI for a toxic collar product (EPA Registration Number 6704-85). By then, the product was called the "Livestock Protection Collar." In 1986, this product was transferred to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). Its new Registration No. became 56228-22. Since 1987, five State-limited registrations have been issued for Livestock Protection Collars. These products permit use of collars in Montana,

New Mexico, South Dakota, Texas, and Wyoming. However, there is no approved training and certification program in South Dakota. A concentrate product registered to APHIS (56228-26) that is limited to use in the manufacture of Livestock Protection Collars and the six registered livestock collar products mentioned above are the only registered pesticide products in the U.S. which legally contain sodium fluoroacetate.

In the mid 1980s, USDI and later APHIS obtained EUPs which authorized field trials with sodium fluoroacetate single-dose baits made of tallow. These baits each contained 5 mg of active ingredient. However, sodium fluoroacetate was never registered for this use pattern.

The rodenticidal uses of sodium fluoroacetate were not directly affected by Executive Order 11643 or by PR Notice 72-2. However, the U.S. Department of the Interior withdrew its sodium fluoroacetate rodenticide products following the issuance of Executive Order 11643. At the time, Tull's 5217-1 product and dozens of intrastate registrations for rodenticidal uses of sodium fluoroacetate remained valid. In 1978, EPA classified all legal uses of sodium fluoroacetate as "Restricted" due to "Acute oral toxicity hazard to nontarget organisms, use and accident history." (Costle, 1978)

In the mid 1970s, EPA placed the non-predacidal uses of sodium fluoroacetate into its RPAR ("Rebuttable Presumption Against Registration") process, the forerunner to what now is called "Special Review." On December 1, 1976, EPA's "Position Document 1" (PD1) was published (41FR52792, 1976). EPA announced a preliminary decision in the RPAR in a second document, the PD 2/3, on November 4, 1983 (Barbehenn, et al, 1983). After consideration of responses to the PD2/3, EPA issued its final decision in the form of a PD4 document in July of 1985 (Anonymous, 1985). The PD 4 called for retention of all rodenticidal uses of sodium fluoroacetate that were permitted at that time, but also imposed significant requirements to modify labels and to supply missing research data. The PD4 represented a significant change in EPA's regulatory position from that taken in the PD 2/3 document, which had recommended cancellation or denial of many uses and modification of all others except those for control of commensal rodents "in and around buildings and ships" (Barbehenn, et al, 1983).

The data call-in issued with the PD4 sought information on the chemistry, residue chemistry, environmental fate, toxicology, and ecological effects of sodium fluoroacetate. The PD4 also dictated that 0.02% was the highest active ingredient strength that could be used for prairie dog control, where such use was permitted, and for ground squirrel control within the range of the California condor. EPA gave registrants whose products were used in such areas the option of developing efficacy data "to establish the lowest effective concentration" if the 0.02% level did not appear to be effective (Anonymous, 1985). The Agency reserved the right to modify the decisions reached in the PD4.

Tull's product 5217-1 was canceled "by operation of law on February 18, 1986" (Yost, 1989) because the company did not respond to a November 22, 1985, "Notice of

Intent to Cancel" (Campt, 1985) requiring that an application for amended registration was submitted within 90 days of the letter. Later, other parties indicated that they would provide the data that Tull would not commit to obtain. On November 13, 1986, Tull was granted a registration (5217-2) for a 90% sodium fluoroacetate product that could be used only as a source of active ingredient for registered sodium fluoroacetate products. Along with this registration, EPA issued a schedule for supplying missing data pertaining to Tull's new product.

After two deadlines for submitting data for Tull's new product (5217-2) passed, EPA refrained from taking immediate cancellation action. Instead, EPA met with parties (e.g., end-use registrants, user groups) concerned with the potential loss of a source of sodium fluoroacetate for controlling rodents. After the various meetings had concluded, EPA issued revised data call-ins in December 1987 pertaining to 5217-2 and to the rodenticidal uses of sodium fluoroacetate (Tinsworth, 1987a,b). Due to lack of appropriate responses toward supplying the data required by the 1985 and 1987 data call-ins (Campt, 1988), EPA proceeded toward canceling Tull's manufacturing use concentrate (5217-2). The product was canceled on February 21, 1989 (Yost, 1989). Subsequently, all "special local needs" registrations issued under §24(c) of FIFRA were canceled, and all pending applications for Federal registration of intrastate products containing sodium fluoroacetate were denied. These actions were completed by August 9, 1990 (Campt, 1990).

Regulatory Status of Sodium Fluoroacetate

The currently registered uses of sodium fluoroacetate are strictly limited to livestock protection collars as a predacide in those states which have registrations and EPA approved certification and training programs. Since all other predacidal uses were canceled by the Administrator in 1972, as described above in the regulatory history, additional predacidal uses cannot be granted without observation of the procedures for reconsidering cancellation decisions set forth in 40 CFR Part 164, Subpart D.

Under the provisions of Subpart D, an application for a new predicidal use of sodium fluoroacetate would require the submission by an applicant of substantial new evidence which might have affected the cancellation decision and could not have been made available to the Administrator during the prior proceeding. In addition, Subpart D requires that the Administrator conduct a hearing before granting reconsideration of the 1972 cancellation decision.

U.S. Regulatory History of Fluoroacetamide

Fluoroacetamide (Compound 1081) was first registered as a pesticide in the U.S. in 1972. In 1976, EPA began an RPAR for this compound because of potential hazards to humans and nontarget animals. In 1978, all uses of fluoroacetamide were classified as "Restricted" because of "acute oral toxicity" (Costle, 1978) and the absence of a true

antidote. In 1979, label changes were adopted to address the Agency's most critical concerns by limiting use of the sole registered product to sewers. As a result, the RPAR process with respect to this chemical was concluded (PD2, Feb. 28, 1980 - 45FR 13189). Fluoroacetamide ultimately was canceled in 1989 after the registrant of the only product failed to pay the registration maintenance fee.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Sodium fluoroacetate is a sodium salt of fluoroacetic acid which is a tan colored alkaline powder with a pH of 10.3. This is probably due to the sodium hydroxide impurity. It melts at 197-203°C with decomposition. It is soluble in water but practically insoluble in all non-polar solvents. Sodium fluoroacetate is stable in sunlight, at a temperature of 54°C, and in tin coated metal containers.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on sodium fluoroacetate is adequate and will support reregistration eligibility.

a. Acute Toxicity

Table 2. Acute Mammalian Toxicity

TEST	RESULTS	CATEGORY
Oral LD50--rat	LD_{50} 0.22 mg/kg	I
Dermal LD50--rabbit	LD_{50} 277.1 mg/kg M; 324.2 mg/kg F	II
Eye irritation--rabbit	slight irritation	III
Dermal irritation--rabbit	not irritating	IV

An acute oral toxicity study with rats used 90.0% sodium fluoroacetate. The LD_{50} was 0.22 mg/kg, which is toxicity category I (MRID 40016971). An acute oral toxicity study with coyotes used doses of sodium fluoroacetate diluted with water. The LD_{50} was 0.12 mg/kg sodium fluoroacetate, which is toxicity category I (MRID 00065627). Literature reports have indicated oral LD_{50}s of 0.10 mg/kg for rats, 0.50 mg/kg for mice, 0.066 mg/kg for dogs, and 0.34 mg/kg for rabbits. The human oral LD_{lo} has been reported as 0.714 mg/kg, and the potentially toxic dose for humans has been stated as 0.5-2.0 mg/kg (Sax and Lewis, 1989).

An acute dermal toxicity study with rabbits used technical sodium fluoroacetate. The LD_{50} was 277.1 mg/kg for males and 324.2 mg/kg for females. The animals showed lethargy, diarrhea, and convulsions preceding death, along with extensive hemorrhage of the thymus and congestion of the lungs. This is toxicity category II (MRID 152129).

A primary eye irritation study used a 1.0% aqueous solution of sodium fluoroacetate with rabbits. There was slight irritation and slight chemosis, which is toxicity category III (MRID 40402603). A primary dermal irritation study also used a 1.0% aqueous solution on rabbits. There was only transient slight edema on one rabbit and the compound was considered not irritating (MRID 40402604).

Requirements for acute inhalation toxicity and dermal sensitization studies were waived due to the severe acute toxicity of the compound and the restriction of its use in a livestock protection collar.

b. Subchronic Toxicity

Technical sodium fluoroacetate was administered by gavage for 13 weeks to Crl:CD(SD)Br rats. The doses were 0, 0.05, 0.20, or 0.50 mg/kg/day. The NOEL was 0.05 mg/kg/day. The LOEL was 0.20 mg/kg/day, based on dose-related findings in histopathology (hypospermatogenesis, fusion bodies, and immature or abnormal sperm) and decreased size and weight of testes and epididymides in males. Females had dose-related increases in absolute and relative heart weights at the mid and high doses (Wolfe, 1988).

In a study with male Sprague Dawley rats, the animals were dosed with 0, 0.07, 0.19, or 0.71 mg/kg/day of sodium fluoroacetate in their drinking water for seven days. This was followed by 21 days without the test compound. A group of rats from each dose level was killed each day of treatment and on days 3, 7, 14, and 21 after dosing. The testes, kidneys and liver were examined. Testicular atrophy and nonreversible tubular degeneration were found at the mid and high dose. Testicular atrophy with reversible tubular degeneration was found at the low dose. No effects on liver or kidney were seen. The lowest dose was the LOEL (MRID 40016990).

c. Metabolism

Fluoroacetate in the mammalian body is converted to fluorocitrate. This compound inhibits the enzyme aconitase, thus blocking the citric acid cycle. This leads to accumulation of citric acid, which may cause

convulsions and death from cardiac failure or respiratory arrest (Gribble, 1973).

Sodium fluoroacetate can be absorbed through the gastrointestinal tract, respiratory tract, or open wounds, but only slowly through intact skin (Sax and Lewis, 1989).

d. Reference Dose

The RfD was determined to be 0.00002 mg/kg/day. This was based on the 13-week subchronic oral rat study, in which the NOEL was 0.05 mg/kg/day. An uncertainty factor of 3000 was used to account for interspecies extrapolation, intraspecies differences, and lack of additional studies (Ghali, 1994).

2. Exposure Assessment

a. Dietary and Occupational/Residential Exposure

Under the current permitted use pattern there will be no sodium fluoroacetate exposure to the general population. Based on the use information, there are no applicator/mixer/loader or post-application exposure concerns other than following the label restriction for use by certified personnel only.

3. Risk Characterization

a. Toxicological Endpoints

Because of the specific nature of this registered use, the primary concern is for the potential risk of acute toxicity.

b. Occupational and Residential

There are no uses of sodium fluoroacetate in residential environments. Based on the use information, potential risk for acute toxicity to workers exposed to sodium fluoroacetate is not expected.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the hazard of sodium fluoroacetate to nontarget organisms.

a. Toxicity to Terrestrial Animals

In order to establish the acute and subacute toxicity of sodium fluoroacetate to birds, the following tests were required using the technical grade material: one avian single-dose oral LD_{50} study on one species; the bobwhite quail (Colinus virginianus) or preferably the mallard duck (Anas platyrhyncos); two subacute dietary LC_{50} studies on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably the bobwhite quail or the ring-necked pheasant (Phasianus colchicus).

(1) Birds, Acute and Subacute

Acute oral toxicity

The acute oral LD_{50} value for the technical grade of sodium fluoroacetate for avian species has been reported in the literature. Hudson et al. (1984) reported the acute oral LD_{50} values for the ring-necked pheasant, mallard duck and chukar (Alectoris graeca) to be 6.4 (95% C.I. = 3.85-10.8), 9.1 (95% C.I. = 5.6-14.6) and 3.51 (95% C.I. = 2.58-4.78) mg/kg, respectively. Ward and Spencer (1947) determined the acute lethal doses for numerous avian species and reported LD_{50} values as low as 3.0, 5.0, and 15 mg/kg for the widgeon (Mareca americana), golden eagle (Aquila chrysaetos), and black vulture (Cartharista urubu), respectively. Atzert (1971) reported the LD_{50} for the black-billed magpie (Pica pica) to be 1 mg/kg. In addition, the USDA conducted a series of acute oral LD_{50} tests on the magpie to get toxicity data for a species that is likely to scavenge the carcasses of coyotes and/or livestock (Burns and Connolly, 1992). Results of these studies showed that the acute oral LD_{50} for the magpie ranged from 1.78 mg/kg to 2.3 mg/kg, depending on temperature and season.

These data indicate that sodium fluoroacetate is very highly toxic to avian species on an acute oral basis. The guideline requirements for this test have been satisfied. Table 3, below is a data summary for the acute toxicity of sodium fluoroacetate to avian species.

Table 3.

AVIAN ACUTE ORAL TOXICITY DATA		
Species	LD_{50} mg/kg	Conclusions
Mallard duck	9.1	highly toxic
Chukar	3.5	highly toxic
Ring-necked Pheasant	6.4	highly toxic
Widgeon	3.0	highly toxic
Golden eagle	5.0	highly toxic
Black vulture	15.0	highly toxic
Black-billed Magpie	1.0 - 2.3	highly toxic

Subacute dietary toxicity

Campbell et al. (1994) reported that the avian dietary LC_{50} values of sodium fluoroacetate for the mallard duck and bobwhite quail were 231 (95% C.I. = 150-338) and 486 (95% C.I. = 339-696) ppm, respectively (MRID #s 43210602; 43210601). Based on these data, sodium fluoroacetate can be classified as highly toxic to avian species on a dietary basis. The guideline requirements for a dietary study have been satisfied. Table 4 is a data summary for the dietary toxicity of sodium fluoroacetate to avian species.

Table 4.

AVIAN SUBACUTE DIETARY TOXICITY DATA		
Species	LC_{50} ppm	Conclusion
Bobwhite quail	486	highly toxic
Mallard duck	231	highly toxic

(2) Birds, Chronic

Substantial chronic exposure to birds is not expected with use of the sodium fluoroacetate livestock protection collar.

(3) Mammals

Wild mammal testing may be required for a pesticide depending on the results of the lower tier studies such as acute and subacute testing and on the intended use pattern and pertinent environmental fate characteristics. Because the livestock protection

collar is specifically designed to kill a wild mammal (coyote), wild mammal toxicity testing has been required for sodium fluoroacetate.

Ward and Spencer (1947) determined the acute lethal doses of sodium fluoroacetate for numerous mammalian species and reported LD_{50} values as low as 0.1 mg/kg for both the cotton rat (Sigmodon hispidus) and coyote (Canis latrans). They also reported that the LD_{50} for the deer mouse (Peromyces sp.) was 4.0 mg/kg. Beasom (1982) reported that the LD_{50} values for the opossum (Didelphis virginiana) and raccoon (Procyon lotor) were 41.6 and 1.1 mg/kg, respectively. Atzert (1971) reported that the LD_{50s} of sodium fluoroacetate to the striped skunk (Mephitus mephitus) and opossum are 1 and 60 mg/kg, respectively. These data indicate that sodium fluoroacetate can be classified as very highly toxic to mammals on an acute oral basis. The guideline requirement for the wild mammal toxicity test has been satisfied. Table 5 is a summary for the acute toxicity of sodium fluoroacetate to mammals.

Table 5.

MAMMALIAN ACUTE TOXICITY DATA		
Species	LD_{50} mg/kg	Conclusions
Coyote	0.1	highly toxic
Cotton rat	0.1	highly toxic
Deer mouse	4.0	highly toxic
Raccoon	1.1	highly toxic
Opossum	41.6	highly toxic
Skunk	1.0	highly toxic

(4) Insects

Data are not required on toxicity to insects, on the basis of negligible exposure associated with the sodium fluoroacetate livestock protection collar.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study

should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Collins (1993) reported that the 96-hour LC_{50} values of technical grade sodium fluoroacetate to the rainbow trout (Oncorhynchus mykiss) and bluegill sunfish (Lepomis macrochirus) were 54 mg a.i./l and > 970 mg a.i./l, respectively. When no substantial mortality occurs at the highest dose evaluated, the LC_{50} is reported as greater than that dose. Based on these data, sodium fluoroacetate can be classified as slightly toxic to coldwater fish species and practically non-toxic to warm water fish species. The guideline requirements for freshwater fish toxicity tests have been satisfied (MRID# 42961601, 42961602). Table 6 is a summary for the toxicity of sodium fluoroacetate to freshwater fish.

Table 6.

FRESHWATER FISH ACUTE TOXICITY DATA		
Species	96-hour LC_{50}(mg a.i./l)	Conclusions
Rainbow trout	54	slightly toxic
Bluegill sunfish	970	practically non-toxic

(2) Freshwater Invertebrates

The minimum testing required to assess the toxicity of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using the first instar Daphnia magna or early instar amphipods, stoneflies, mayflies, or midges (Chironomus sp.).

Collins (1993) conducted an acute static toxicity test on daphnids and determined that the 48-hour EC_{50} of sodium fluoroacetate was 350 mg a.i./l (MRID# 42961603). Based on these data, sodium fluoroacetate can be classified as practically non-toxic to freshwater invertebrates. The guideline requirement for the freshwater toxicity test has been satisfied. Table 7 is a summary for the toxicity of sodium fluoroacetate to freshwater invertebrates.

Table 7.

FRESHWATER INVERTEBRATE TOXICITY DATA		
Species	48-hour EC50 (mg a.i./l)	Conclusions
Daphnia magna	350	practically non-toxic

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine or estuarine environment or is expected to reach that environment in significant concentrations. The terrestrial non-food use of sodium fluoroacetate will not result in substantial exposure to the estuarine environment. Therefore, these data are not required.

c. Toxicity to Plants

Toxicity data are not required for terrestrial, semiaquatic, or aquatic plants for sodium fluoroacetate because the chemical is not a herbicide, is not applied aerially, and there is no other apparent basis for a phytotoxicity concern.

2. Environmental Fate

The Agency has reviewed all literature submitted on environmental fate properties, including studies not required for the livestock protection collar use. No acceptable guideline studies for hydrolysis or other fate properties have been submitted. Four published articles on environmental fate were submitted by the Texas Department of Agriculture in support of an emergency exemption, and 13 published or unpublished articles were submitted in 1986 by the State of California. These articles were found to be lacking significant data and of uncertain value, and therefore not, acceptable as guideline studies. If any new uses of sodium fluoroacetate are proposed, acceptable environmental fate studies may be required.

a. Environmental Fate Assessment

The fate properties of the chemical are characterized to the extent possible, recognizing the limitations of the available data. The conclusions are very tentative relative to an evaluation that could be made if guideline studies were available.

The limited data available suggest that leaching and metabolism are the major routes of dissipation. However, undegraded fluoroacetate is considered mobile and consequently has a high potential to move downward in the soil and reach ground water.

Sodium fluoroacetate appears to degrade primarily by biologically mediated processes. Sodium fluoroacetate appears first to ionize to sodium and fluoroacetate with the fluoroacetate portion further degrading by biologically mediated processes. Microorganisms capable of dehalogenating compounds are reported to metabolize fluoroacetate to fluoride and glycolate faster than other microorganisms. Unvalidated data suggest that sodium fluoroacetate does not degrade substantially in 27 days in sterile soil.

Because there are no leaching adsorption-desorption data, mobility can only be assessed on the basis of solubility in water. Based on solubility in water, undegraded fluoroacetate may tend to leach. However, the potential for leaching may be reduced in some soils by adsorption to organic matter and clay particles and absorption by plants.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis (161-1)

Three published articles have been submitted to the Agency to support the hydrolysis data requirement. These articles were found to be lacking significant data and of uncertain value, and therefore, not acceptable to fulfill the hydrolysis guideline requirement. However, the Agency is not requiring a new hydrolysis study because of the limited amount of sodium fluoroacetate that is used annually in the livestock protection collars, as noted Section II.C. (MRID 00061751, 40016958, 40016959)

Based on one of these published articles the stability of sodium monofluoroacetate in water and saline was determined for a period of approximately 6 months. An immediate loss of fluorine was detected in both the water and saline solutions. A progressive loss of fluorine was reported in the water solutions. However, the saline solutions indicated no significant decreases in fluorine content after the initial loss. The chemical reaction was not further addressed in the first of the articles by Goldman (MRID 00061751). However, other articles indicate the following reaction:

$$XCH_2COO^- + OH = HOCH_2COO^- + X^-$$

(where X = F, Cl, or I)

c. Water Resources

(1) Ground Water

For terrestrial uses, the published or unpublished data indicate that small quantities of sodium fluoroacetate have the potential to reach groundwater. The Agency's Pesticides in Ground Water Database reports no detections for the period 1971 to 1991.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

(1) Exposure and Risk to Nontarget Terrestrial Animals

Certain nontarget species of birds and mammals including endangered and non-endangered species may be exposed by the following mechanisms:

Primary hazard

- Contaminated sheep or goat carcasses with either broken (punctured) or unbroken collars.
- Toxicant spilled on the ground or vegetation when a collar is punctured.

Secondary hazard

- Carcasses of coyotes killed by the sodium fluoroacetate livestock protection collars and not removed.
- Vomitus of poisoned coyotes. (The chemical has emetic properties)

Based on a variety of studies that have been reviewed by the Agency, the principal source of risk is exposure of scavengers feeding on the head and neck area of dead livestock bearing the sodium fluoroacetate livestock protection collars. The other sources of exposure identified above are not likely to result in unacceptable risk. Factors that reduce the risk associated with use of the sodium fluoroacetate livestock protection collars include rapid decomposition of carcasses, selective feeding of scavengers from

wounds on the carcass rather than contaminated skin surface of the head or neck, and the emetic property of the chemical. The concerns for risk to wildlife can be addressed with applicators following environmental hazard statements, special use restrictions, and endangered species protection statements that are required to be placed on the label.

The following is a review of information that applies to the risks to both birds and mammals, which may be exposed by similar mechanisms.

Risk from exposure to livestock carcasses bearing livestock protection collars.

The information available suggests that the greatest risk to nontarget species is from exposure to the neck areas of livestock carcasses bearing the sodium fluoroacetate livestock protection collars.

Knowlton and Ebbert (1991) used radiolabeled sodium fluoroacetate as a physiological marker to determine the amount of toxicant likely to be consumed by a coyote and the amount likely to occur on the necks of collared goats (Capra sp.) when the coyotes attacked the goats and punctured the collars that contained 30 ml of the toxicant. The volume of fluid dispensed from the collar was 19.2 ml on average (range 11.9 to 27.8 ml); the average volume ingested by the coyote was 1.0 ml (0.1 to 2.9 ml). The average amount of toxicant contaminating the neck of the goat was 75 mg (39 to 118 mg). The average amount of toxicant not recovered was 113 mg (0 to 234 mg). Once punctured, the pouches discharged over 85% of their contents within a short time period. Relatively little of the toxicant was actually ingested by the coyotes with 6 of 15 coyotes ingesting less than 5 mg when killing the goat.

Savarie et al. 1990 also studied contamination of the necks of collared lambs (Ovis sp.) killed by coyotes. They found that 12 contaminated sheepskins contained an average of 96 mg sodium fluoroacetate with a range of 23 to 200 mg.

Comparison of the two studies just cited (Knowlton and Ebbert, 1991; Savarie et al. 1990) suggests that the amount of toxicant on the necks of collared livestock is similar for goats and sheep. The average amount of sodium fluoroacetate released from the collar was 130 mg in the goat study (Knowlton and Ebert) and

135 mg for the sheep study (Savarie et al.). The amount not recovered was 5.6 mg for the goat study and 6.1 mg in the sheep study.

In the Knowlton and Ebbert study, the average amount of fluid contaminating the neck of the goat was 7.5 ml (3.9 to 11.8 ml), or about 75 mg toxicant. That level clearly exceeds toxicity values for numerous birds and mammals that could scavenge the carcass, which suggests that the primary hazard to the scavengers is quite high. However, field studies reviewed subsequently suggest that mortality to scavengers feeding on the carcasses is actually minor. For example, it has been observed that vultures, magpies, ravens (Corvus corax), red-tailed hawks (Buteo jamaicensis), caracaras (Polyborus cheriway), coyotes, and skunks all scavenged the carcasses of collared livestock killed by coyotes, but none appeared to have been poisoned (USDA/APHIS, 1991; Connolly, 1980; Littauer, 1983).

Several factors may account for the apparent discrepancy between the field results and the implications of residue measurements. First, the typical behavior of scavengers is to feed at wounds or openings in the carcass or where the skin has been torn away from the carcass, rather than on the contaminated neck area. This tendency may greatly reduce the likelihood of exposure to avian species such as the bald eagle (Haliaeetus leucocephalus) (USFWS, 1984, 1985). Connolly (1980) simulated exposure to non-target animals with a series of tests exposing magpies and domestic dogs (Canis familiaris) to collared livestock killed by coyotes. Both dogs and magpies fed heavily on the carcass but neither were poisoned. Connolly further observed that both the species tended to feed on parts where the coyote had previously fed rather than on the neck area where the highest contamination is likely. They concluded that typical feeding behavior of scavengers confers a degree of protection against accidental poisoning by livestock collars.

Secondly, toxicity data suggest that birds likely to scavenge, particularly raptors, tend to be less sensitive to sodium fluoroacetate than mammals, especially canids (Haegele et al., 1984; Ward and Spencer, 1947 and Atzert, 1971). Also, emesis has been observed as an early symptom of sodium fluoroacetate poisoning (Ward and Spencer, 1947) and may cause certain raptors to discontinue feeding before lethal amounts are absorbed (Dana, 1971). The emetic property of sodium fluoroacetate is likely to reduce exposure to

raptors scavenging on livestock, and probably will also make the raptors less likely to continue feeding on them.

Another factor that can greatly influence the primary hazard, especially in warm weather, is that livestock carcasses decompose rapidly under field conditions, rendering them unpalatable to many avian and mammalian species (Burns et al., 1984 and Connolly, 1980).

Risk from lost or spilled toxicant

Knowlton and Ebbert (1991) found that the average volume of fluid not recovered was 11.3 (0-23.4) ml or approximately 113 mg sodium fluoroacetate, which is nearly 33% of the total amount in the 30 ml collar. It is believed that most of the fluid not recovered is spilled on the ground. The available fate information consists largely of studies that were not found to be acceptable. Nevertheless the available information on fate properties suggests that sodium fluoroacetate tends to be absorbed rapidly to organic material and tends to degrade rapidly in soil. The Agency believes that there is no substantial hazard to non-target organisms from the sodium fluoroacetate that spills on the ground as a result of the collar being punctured by an attacking coyote.

Risk from consumption of tissue, stomach contents, or vomitus of coyotes killed by the sodium fluoroacetate livestock protection collars

Connolly (1980) evaluated sodium fluoroacetate residues in muscle of captive coyotes that received known oral doses. At a known oral dose of 5.0 mg the concentration in muscle was determined to be 0.10 ppm while the 10 mg dose resulted in a concentration of 0.19 ppm. Based on this relationship a coyote that ingests an average of 1 ml fluid (10 mg toxicant) will have muscle tissue residues of 0.19 ppm sodium fluoroacetate. The highest sodium fluoroacetate residue level found in muscle tissue was 0.93 ppm.

Residues in coyotes that have killed sheep wearing the 30 ml collar have been determined by Burns et al. (1984). Those authors report average concentrations of 0.15 ppm in muscle, 0.5 ppm in stomach contents, and 0.35 ppm in vomitus. The highest residue found occurred in the stomach contents and was 2.3 ppm.

Knowlton and Ebbert (1991) analyzed muscle tissue from 10 coyotes that were killed as a result of puncturing collars. Residues were detected in the muscle of all the coyotes. The concentration in muscle tissue was 0.089 ppm (range of 0.05 to 0.280 ppm); the mean ± SE sodium fluoroacetate lost from 12 collars was 92 ± 56 mg (range 3 to 183 mg).

Table 9 below gives estimates of the amount of muscle tissue, stomach contents, or vomitus, from coyotes killed with the 30 ml sodium fluoroacetate livestock protection collar that would have to be consumed in order for a scavenger to ingest an LD_{50} (Burns et al., 1984). These data suggest that secondary hazard to to animals that may feed on a contaminated coyote carcass is ordinarily not substantial (Burns et al., 1984; Connolly, 1980; Knowlton and Ebbert, 1991). However, it is likely that carcasses will occasionally contain enough sodium fluoroacetate to kill a scavenger. The results below represent average exposures. The data suggest substantial variation from one carcass to the next. This qualification has to be considered when interpreting statements in the following assessments related to muscle tissue, vomitus, and stomach contents.

Table 9.

Approximate amounts of tissue from coyotes killed with the 30 ml sodium fluoroacetate livestock protection collars that scavengers would have to consume to obtain an LD_{50} of sodium fluoroacetate.

Species	Average weight (kg)	LD_{50} mg/kg	LD_{50} dose (mg)	Muscle 0.15 ppm (kg)	Stomach 0.5 ppm (kg)	Vomit 0.35 ppm (kg)
Black vulture	2.0	15.0	30	200	60	85.7
Golden Eagle	4.54	5.0	22.7	151	45.4	64.8
Black-Billed Magpie	0.18	1.0	0.18	1.2	0.36	0.51
Coyote	11.4	0.1	1.14	7.6	2.28	3.25
Skunk	3.18	1.0	3.18	21.2	6.36	9.08

Muscle Tissue

Most species would have to consume considerable contaminated tissue, relative to their body weight, to obtain a lethal dose. For example, black vulture, golden eagle, and black-billed magpie would have to consume 100×, 33×, and 6.6× their body

weights, respectively, to obtain an LD_{50} dose from muscle tissue. Even a coyote, the most sensitive species tested, would have to eat approximately 67% of its body weight to get an LD_{50} dose.

Stomach Contents

Black vulture, golden eagle, and black-billed magpie would have to consume 30×, 10× and 2× their body weight, respectively, to obtain an LD_{50} dose from stomach contents. Because of the higher concentrations in stomach contents, species that feed primarily on the viscera may be at greater risk than those that feed primarily on muscle.

Vomitus

Clinical observations suggest that sodium fluoroacetate is emetic especially to canids which have ingested more than an LD_{50} [Ward and Spencer, 1947 and Texas A&M University System (TAMUS), 1983]. Observations of coyote behavior made during the TAMUS study also found that some coyotes would cache the vomitus, which may further reduce exposure to animals that would otherwise eat it. Connolly (1980) reported that concentrations in vomitus of four poisoned coyotes ranged from below the detection limit (0.1 ppm) to 0.72 ppm. The average concentration in vomitus from five coyotes that attacked sheep wearing the 30 ml collar has been reported to be 0.35 ppm (USDA/APHIS, Unpublished Report, 1986). These levels may be toxic to certain species that are very sensitive to sodium fluoroacetate; however, the Agency considers it unlikely that sufficiently large amounts of vomitus would be available or found by non-target animals under field conditions to exceed the Agency's risk criteria. For example, the coyote would have to consume about 29% of its body weight to obtain a LD_{50} equivalent from vomitus. The skunk would have to consume 280% of its body weight.

Burns et al. (1986) also studied residues in coyotes killed with single drop baits (SDBs) treated at 5 mg/bait. They found average concentrations of 0.29 ppm for muscle, 0.30 ppm for small intestine, and 0.31 ppm for stomach. They concluded that these values were consistent with those found in the 30 ml sodium fluoroacetate livestock protection collars study conducted by Connolly (1980). They also conducted a series of feeding tests to determine if there was any potential for secondary hazard to non-target animals that fed on coyotes poisoned by the SDBs. All of the

removed tissue except the gastrointestinal tract was fed to 3 dogs (Canis familiaris), 3 coyotes, 4 striped skunks and 15 magpies for periods ranging from 14 to 35 days. The total amount of contaminated tissue consumed, and expressed as percent of body weight averaged 67% for dogs, 152% for coyotes, 117% for skunks and 371% for the magpies. None of the test species exhibited any signs of sodium fluoroacetate poisoning or had any detectable sodium fluoroacetate residues in there tissues. Again, these data indicate that even if non-target species feed on carcasses of coyotes killed by the collar, it is highly unlikely that they will ingest sufficient quantities of contaminated tissue to result in a secondary hazard.

Finally, the U.S. Fish and Wildlife Service was required to evaluate secondary hazard to non-target organisms resulting from use of the 30 ml sodium fluoroacetate livestock protection collars. To simulate secondary poisoning, coyotes were administered doses of 4 mg, 100 mg, and 400 mg of sodium fluoroacetate. Upon death, all the coyotes were skinned and eviscerated and all muscle tissue was removed from the skeletons. All the tissue except the gastrointestinal tract was ground up and fed to stripped skunks, raccoons and opossums. The results indicated that only the carcasses of animals that had received more than 200 mg of sodium fluoroacetate would be expected to place scavengers at risk and that the only species of scavengers that would be expected to be at risk would be those with relatively low tolerance for the chemical (TAMUS, 1983). The dosages that caused observable effects greatly exceeded those administered to the coyote by the sodium fluoroacetate livestock protection collars, indicating that mortality to non-target animals is unlikely from operational use of the collar.

Total Collar Use

In addition to the residue information, it is important to consider how many collars will typically be used in coyote control operations. Based on the results of field studies conducted in various states, it appears that the numbers of collars used and the amounts of sodium fluoroacetate actually lost to the environment are both quite low. For example, in the study conducted in New Mexico only 23 of 330 of the collars (or 7%) were ever punctured. Of those 23 collars only 5 (or 22%) were punctured by coyotes (Littauer, 1991). The remaining 18 collars were punctured from vegetation or unknown causes.

During three years of monitoring in Wyoming, Montana, Texas, and New Mexico only 294 out of 2257 collars (13%) were punctured and had their contents released. Assuming that each collar was completely emptied, the amount of sodium fluoroacetate released to the environment would be 88.2 grams, or an average of 29.4 grams/year over the four state area where the collars were used. What is even more significant is that only 108 of the 294 collars punctured, or 36.7%, were punctured by coyotes. The total amount of sodium fluoroacetate released from collars punctured by coyote attacks (assuming that each collar was emptied) was 32.4 grams or an average of only 10.8 grams/year over the four state area. Nearly as many collars (80 collars or 4%) were punctured from vegetation and unknown causes as from coyote attacks.

Field Studies

From 1978 to 1980, the U.S. Fish and Wildlife Service conducted field research in various states to assess primary and secondary hazards from the use of the sodium fluoroacetate livestock protection collars (Connolly, 1980). It was found that the primary scavenger of collared goats that were killed by coyotes in Texas were turkey vultures (Cartharista aura) and black vultures, while red-tailed hawks, caracaras and ravens infrequently scavenged kills. No scavenging by mammals was observed. In Montana and Idaho, black-billed magpie was the species observed most frequently as a scavenger of sheep killed by coyote. Scavenging by ravens was observed infrequently. In addition the following summary is given for primarly poisoning:

"In summary, coyote-killed collared livestock were known to have been scavenged by turkey vultures, black vultures, magpies, ravens, red-tailed hawks, caracaras, a skunk and a coyote during the present studies. No scavenger was known or believed to have been poisoned. Scavengers ignored the collars and fed instead upon the viscera and muscle that has been exposed by the killer coyote."

Field observations of secondary poisoning studies, conducted in Texas and Montana showed that turkey vultures were the only scavengers of dead coyotes although numerous other scavengers such as golden eagles, ravens, magpies, skunks and other potential scavengers were abundant in the area.

From 1981 to 1983, the New Mexico Department of Agriculture conducted an experimental field program evaluating the

efficacy and safety of the toxic collar. A total of 330 collars were used over approximately 1,000 days. Twelve collared lambs were attacked, but only 5 collars were actually punctured by predators. A total of 18 collars were accidentally punctured while 21 collars were lost. Three predators were found dead, two coyote and one bobcat (Lynx rufus). The only non-target animal believed to have been poisoned during the study was a skunk. The results of this study suggest that exposure of non-target species by feeding on the coyote carcass or the neck area of the collared livestock was low and did not result in any significant adverse effects (Littauer, 1983).

As part of the registration requirements, the USDA/APHIS was required to submit information on hazard to non-target species resulting from the use of the 30 ml sodium fluoroacetate livestock protection collars, collected as a result of use of the device in Montana, Wyoming, New Mexico, South Dakota and Texas (USDA/APHIS, 1991). The major findings from the actual use of the collar during 1988, 1989 and 1990 as well as a report on the field and laboratory research conducted from 1978 to 1980 are as follows:

- The contents of a small portion (13%) of the collars placed on livestock were actually released into the environment. The total amount of sodium fluoroacetate involved in the release, assuming that each collar was completely emptied, was 88.2 grams. This is an average of 29.4 grams/year over the four state area where the collars were used. (No collars were used in South Dakota.)

- There were no reports of deaths of non-target animals associated with the use of the sodium fluoroacetate livestock protection collars during this period.

- Only limited scavenging occurred on coyote carcasses. Scavenging was reported by caracara and two species of vulture.

- Livestock carcasses were scavenged by vultures, magpies, ravens, red-tailed hawks, caracaras, skunks and coyotes, but none of these non-target species were known to have been poisoned as a result.

- Scavenger species tended to feed mainly on viscera and muscle of hind quarters.

- Of the 13% of the collars that had their contents released during the time period (or 294 collars), only 5% (108 collars) were punctured by coyotes.

(a) Birds

The chemical is very highly toxic to birds on an acute oral basis. Certain bird species may be exposed, primarily as a result of scavenging the carcasses of livestock bearing the sodium fluoroacetate livestock protection collars. The risks are discussed in detail above, generically for nontarget avian scavengers and nontarget mammalian scavengers. The concerns for risk to wildlife can be addressed with the environmental hazard statements, special use restrictions, and endangered species protection statements, that are required to be placed on the label.

(b) Mammals

The chemical is very highly toxic to mammals on an acute oral basis. Certain species may be exposed, primarily as a result of scavenging the carcasses of livestock bearing the sodium fluoroacetate livestock protection collars. The risks are discussed in detail above, generically for nontarget avian scavengers and nontarget mammalian scavengers. The concerns for risk to wildlife can be addressed with environmental hazard statements, special use restrictions, and endangered species protection statements, that are required to be placed on the label.

(c) Insects

Substantial exposure of nontarget insects is not anticipated from the use of the sodium fluoroacetate livestock protection collars.

(2) Exposure and Risk to Nontarget Aquatic Animals

Based on low toxicity to aquatic animals and low exposure associated with use of the sodium fluoroacetate livestock protection collars, the Agency finds that use of the collar is not likely to result in unacceptable risk. Sodium fluoroacetate is practically non-toxic to warmwater fish species and aquatic invertebrates, and only

slightly toxic to coldwater fish species. The Agency does not have reports of detections in surface or ground water.

(3) Exposure and Risk to Nontarget Plants

Evaluation of exposure and risk is not required for terrestrial, semiaquatic, or aquatic plants because sodium fluoroacetate is not a herbicide and is not applied aerially, and there is no other apparent basis for a phytotoxicity concern.

(4) Endangered Species

On March 21, 1985, the Agency requested formal Section 7 consultation relative to the United States Department of Interior's application to register compound sodium fluoroacetate livestock protection collar. On June 14, 1985, the U. S. Fish and Wildlife Service - Office of Endangered Species (USFWS-OES) responded and concluded that the use of the sodium fluoroacetate collar with proposed use directions and restrictions posed no jeopardy to the bald eagle, San Joaquin kit fox, black-footed ferret (Mustela nigripes), and gray wolf (Canis lupus), but was likely to jeopardize the continued existence of the grizzly bear (Ursus arctos horribilus), Rocky Mountain wolf (Canis lupus irremotus) and California condor (Gymnogys californianus) (USFWS, 1985). The USFWS-OES provided specific state and county recommendations for avoiding adverse effects to the non-jeopardy species as well as reasonable and prudent alternatives for precluding jeopardy to the three species in jeopardy from the use pattern. Based on these recommendations, the Agency developed specific endangered species label precautions and use restrictions for the 30 ml collar. These use restrictions have been included in a Technical Bulletin that accompanies the labeling.

In 1987, as a result of informal consultation with field operations personnel from the USFWS, the Agency became aware that additional precautions, specifically addressing the use of the sodium fluoroacetate livestock protection collars in Texas, were required to protect the ocelot (Felis pardalis) and jaguarundi (Felis yagouarundi cacomitei) (USFWS, 1986). The additional use precautions were reviewed by the Agency and included in the Technical Bulletin.

In March 1993 the USFWS issued a final biological opinion on the effects of 16 vertebrate control agents on threatened and endangered species. This opinion specifically addressed the livestock protection collar and included jeopardy determinations to the gray wolf and grizzly bear. It did not conclude jeopardy determinations to any other species. The USFWS identified specific areas where the collar could not be used and concluded that implementation of such a restriction would preclude jeopardy to both the graph wolf and the grizzly and that no incidental take would occur from the use of the collar. Such restrictions have been incorporated on the livestock protection collar labels.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

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 the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing sodium fluoroacetate active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing sodium fluoroacetate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium fluoroacetate, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of sodium fluoroacetate and to determine that sodium fluoroacetate can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing sodium fluoroacetate as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency 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, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all currently registered uses of sodium fluoroacetate are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing sodium fluoroacetate if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

As described in the Regulatory History and Status section of this document (Section II.E.), and in 40 CFR Part 164, Subpart D, new predicidal uses for sodium fluoroacetate cannot be granted without submission by the applicant of new evidence which was not available and which could have impacted the outcome of the decision in 1972 by the Administrator to cancel the predicidal uses, and without a hearing involving all interested parties.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient sodium fluoroacetate, the Agency has sufficient information on the health effects of sodium fluoroacetate and on its potential for causing adverse effects in fish and wildlife and the environment.

The Agency has determined that sodium fluoroacetate products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing sodium fluoroacetate registered for the sole remaining use are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that the single currently registered use of sodium fluoroacetate is eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for sodium fluoroacetate. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Restricted Use Classification

Sodium fluoroacetate, which is only registered for use in livestock protection collars, will retain the restricted use classification imposed by the Agency in 1978 due to its high acute toxicity and the need for highly specialized applicator training.

2. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered animal species to sodium fluoroacetate as discussed above in the science assessment chapter.

At this time no further measures are necessary for protection of endangered species. Should the use of sodium fluoroacetate change or the Agency becomes aware of new information that would warrant new concerns, the Agency will take additional action as necessary.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data and labeling requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of sodium fluoroacetate for the above eligible use has been reviewed and determined to be substantially complete.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"For use only for reformulating into sodium fluoroacetate solutions for use only in Federally-registered livestock protection collars".

B. End-Use Products

1. Additional Product-Specific Data Requirements

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 product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The use of sodium fluoroacetate in the animal protection collar is currently registered in five states (Montana, New Mexico, South Dakota, Texas, and Wyoming).

The following list of use restrictions for sodium fluoroacetate represents the USDA/APHIS product.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

USE RESTRICTIONS

1. Use of livestock protection (LP) collars shall conform to all applicable Federal, State, and local regulations.

2. LP Collars shall be sold or transferred only by registrants or their agents and only to certified Livestock Protection Collar applicators. Collars may be used only by specifically certified Livestock Protection Collar applicators or by persons under their direct supervision. [1]

   The certified applicator is directly responsible for assuring that all use restrictions are met. The certified applicator will decide, in accordance with label directions, when and under what circumstances collars will be used. The certified applicator will either apply collars or be physically present where collars are applied by a noncertified person. However, a noncertified person who has received adequate instructions from the certified applicator may store collars, check collars in the field, remove collars, repair or dispose of damaged collars in accordance with use restrictions, retrieve collars laying in the field and properly dispose of contaminated material and animal carcasses.

3. Certification of applicators shall be performed by appropriate regulatory agencies. Prior to certification, each applicator shall receive training which will include, but need not be limited to:

   (a) Training in safe handling and attachment of LP collars.

[1] "Direct Supervision," as described in this restriction, conforms to the requirements established under 40 CFR 171.6.

(b) Trainig in disposal of punctured or leaking LP collars, and contaminated animal remains, vegetation, soil, and clothing.
(c) Instructions for practical treatment of 1080 poisoning in humans and domestic animals.
(d) Instructions on record keeping.

4. Registrants or their agents shall keep records of all collars sold or transferred at their address of record. Records shall include the name, address, state where Livestock Protection Collar certification was issued, certification number of each recipient, and dates and numbers of collars sold or transferred.

5. Each applicator shall keep records dealing with the use of LP Collars and the results of such use. Records shall be maintained in accordance with appropriate State or Federal regulations but for not less than two years following disposal or loss of collar. Such records shall include, but need not be limited to:

(a) The number of LP collars attached on livestock.
(b) The pasture(s) where LP collared livestock were placed.
(c) The dates of each attachment, inspection, and removal
(d) The number and locations of livestock found with ruptured or punctured LP collars and the apparent cause of the damage.
(e) The number, dates, and approximate location of LP collars lost.
(f) The species, locations, and dates of all suspected poisonings of humans, domestic animals or non-target wild animals resulting from LP collar use.

6. Any suspected poisoning of threatened or endangered species must be reported immediately (within three days) to the Environmental Protection Agency, as will each suspected poisoning of humans, domestic animals or non-target wild animals. The person to contact at the Environmental Protection Agency is Robert A. Forrest (PM-14), Registration Division (7505C), 401 M Street, SW, Washington, DC 20460.

7. Only the registrant or collar manufacturer is authorized to fill LP collars with 1080 solution. Certified applicators are not authorized to fill LP collars. Compound 1080 solution may not be removed from collars and used for any other purpose.

8. LP Collars shall only be used to take coyotes within fenced pastures[2] no larger than 2,560 acres (4 square miles). But where average annual precipitation does not exceed 20 inches and vegetation is sparse, consisting only of short to mid-height grasses and scattered shrubs, collars may be used in pastures up to a maximum of 10,000 acres (16 square miles) in size.

In no case shall the applicator place LP collared livestock in pastures where compliance with other Use Restrictions, such as monitoring, is impossible; in fenced pastures larger than 10,000 acres; or in unfenced, open range.

9. LP Collars shall be used only where losses of sheep or goats due to predation by coyotes are occurring or, based upon prior experience, where coyote predation can reasonably be expected to occur.

10. Where LP collars are in use, each logical point of access (for example, roads, gates, and trails) shall be conspicuously posted with a bilingual (English/Spanish or other second language appropriate for the region) warning sign not less than 8" X 10" in size. Signs shall be inspected weekly to ensure their continued presence and legibility and will be removed when collars are removed. The signs will have a minimum type size for "DANGER-POISON" of 24 point (1/4 inches), with remaining text at least 18 point (3/16 inches).

11. All LP collared livestock must be checked at least once every seven days and collars adjusted if needed.

    If any LP collared animal is not accounted for in two consecutive checks, an intensive search for it must be made.

    In addition, if more than three LP collared animals are not accounted for during any one check, an intensive search for these animals is required.

    If more than nine (9) LP collars are unaccounted for during any 60 day period, remove all collars from animals and terminate their use. Do not resume use until adequate steps have been taken to prevent further, excessive loss of collars.

[2] Fenced pastures include all grazing land that is enclosed by livestock fencing. This includes wire or other man-made fences such as rock walls, and natural barriers such as escarpments, lakes, and large rivers that will prevent the escape of livestock.

12. Damaged, punctured, or leaking LP collars shall be removed from the field for repair or proper disposal. Damaged collars shall be placed individually in leakproof containers while awaiting repair or proper disposal. Authorized collar repairs are limited to minor repairs of straps and fastenings. Leaking or punctured collars must be properly disposed.

13. Dispose of 1080 wastes (punctured, leaking, or otherwise unrepairable LP collars; contaminated leather clothing, animal remains, wool, hair, vegetation, water, and soil) under three feet of soil, at a safe location, preferably on property owned or managed by the applicator and at least 1/2 mile from human habitations and water supplies. No more than 10 collars may be buried in any one hole. lf buried in a trench, each group of 10 collars must be at least 10 feet apart.
Incineration may be used instead of burial for disposal in the field (preferably on property owned or managed by the applicator) at least 1/2 mile from human habitation and water supplies. Place collars and waste (listed above) in an incinerator or refuse hole, saturate with diesel fuel, and ignite. Attend the burn until the contaminated material is completely consumed.

Alternatively, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in disposing of wastes at approved hazardous waste disposal facilities.

When snow or frozen ground make on-site disposal impractical, up to one cubic foot of wastes may be stored in a leak-proof container in a dry, locked place for 90 days.

Metal Container: Triple rinse contaminated and uncontaminated containers with water. Puncture and dispose of contaminated container and rinsate as above.

Plastic Container: Triple rinse with water. Then puncture and dispose of container and rinsate as above.

14. All persons authorized to possess and use LP Collars shall store them under lock and key in a dry place away from food, feed, domestic animals, and corrosive chemicals and in outbuildings, or in outdoor storage areas attached to, but separate from human living quarters.

15. Provisions for the protection of endangered species:
The LP Collar may not be used in the following areas due to potential adverse effects to endangered species (California condor).

STATE	COUNTIES
California	Fresno, Kern, Kings, Los Angeles, Monterey, San Luis Obispo, Santa Barbara, Tulare, and Ventura

The LP collar may not be used in the following areas without written approval from the nearest U.S. Fish and Wildlife Service Office (FWS, Endangered Species Specialists). If FWS or the user determines that the use of collars may adversely impact an endangered species (San Joquin kit fox, black-footed ferret, Northern Rocky Mountain wolf, or Grizzly bear) in the specific areas requested, collars may not be used in these areas. Written approval must be obtained annually.

State	Counties or Area	NEAREST FWS OFFICE/ PHONE
California	Alameda, Contra Costa, Merced, San Joaquin, Santa Clara, and Satnislaus	Sacramento, CA 916-978-4866
Idaho	Bonner, Boise (north of State Highway 21), Boundry, Clearwater, Custer (north of local road running from Sun Valley to Chilly and a corresponding line northeast from Chilly to Patterson), Fremont, Idaho, Lemhi, Shosshone, and Valley	Boise, ID 208-334-1931
Michigan	Keweenaw (Isle Royal) and entire Upper Peninsula	Twin Cities, MN 612-725-3276

State	Counties or Area	NEAREST FWS OFFICE/ PHONE
Minnesota	Aitkin, Becker, Beltrami, Carlton, Cass, Clearwater, Cook, Crow Wing, Hubbard, Itasca, Kittson, Koochiching, Lake, Lake of the Woods, Mahnomen, Marshall, Pennington, Pine Roseau, and St. Louis	Twin Cities, MN 612-725-3276
Montana	Beaverhead, Carbon, Flathead, Gallatin, Glacier, Lake, Lewis and Clark, Lincoln, Madison, Missoula, Park, Pondera, Powell, Sanders, Stillwater, Sweet Grass, and Teton	Helena, MT 406-449-5322
Washington	Pend Orielle, Okanogan, (National Park and Forrest Land), Skagit, and Whatcom	Boise, ID 208-334-1931
Wisconsin	Douglas, Florence, Lincoln, Oneida, and Price	Twin Cities, MN 612-725-3276
Wyoming	Fremont, Park, and Teton and Yellowstone National Parks	Helena, MT 406-449-5322

16. The number of LP collars used shall be the minimum necessary for effective livestock protection. For pastures of the following size classes, do not use more collars than the number indicated.

Size (acres)	Number of Collars
up to 100	20
101 to 640	50
641 to 10,000	100

17. Each applicator will have a one-ounce bottle of syrup of ipecac (to induce vomiting in case of accidental poisoning) available when attaching, inspecting, removing, or disposing of LP collars.

18. No contaminated animal will be used for food or feed.

In addition, for State-limited products, additional use restrictions consistent with EPA's regulatory position and legal decisions regarding predacidal uses of sodium fluoroacetate may be added. The organization of restrictions may be altered so as to maintain consistency with applicable State and Federal laws and regulations but no requirements may be dropped or mitigated. Any changes to the use restrictions must be requested through the amendment process and must be accepted by the U.S. Environmental Protection Agency before they may be incorporated into the labeling of product released for shipment in the U.S.

Unless the Agency specifically indicates otherwise, the current accepted labeling for registered 1080 Livestock Protection Collar products remains acceptable.

The registrants should submit 5 copies of their last accepted labeling (all 3 componets thereof) with their 8-months responses. The Agency will then review the documents to determine whether any changes are needed.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Registration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell sodium fluoroacetate products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, for 26 months from the date of issuance of this RED. Registrants and persons other than the registrants remain obligated to meet preexisting Agency imposed label changes and existing stocks requirements applicable to your products.

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
DAIRY GOATS (LACTATING OR UNSPECIFIED)									Use Group: INDOOR FOOD		
Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	013	C20, CAL
Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.											
	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	MT	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	NM	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	SD	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	TX	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	WY	C20, CAL
GOATS (MEAT)									Use Group: INDOOR FOOD		
Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	013	C20, CAL
Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.											
	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	MT	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	NM	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	SD	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	TX	C20, CAL

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
GOATS (MEAT) (con't)				Use Group: INDOOR FOOD (con't)							
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		WY	C20, CAL
KIDS (MEAT)				Use Group: INDOOR FOOD							
Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS NS	NS	NS	NS	013		C20, CAL Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.
	FM/L	NA	6.650E-04 lb collar	*	NS NS	NS	NS	NS		MT	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		NM	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		SD	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		TX	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		WY	C20, CAL
LAMB (MEAT)				Use Group: INDOOR FOOD							
Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS NS	NS	NS	NS	013		C20, CAL Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.
	FM/L	NA	6.650E-04 lb collar	*	NS NS	NS	NS	NS		MT	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS NS	NS	NS	NS		NM	C20, CAL

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
LAMB (MEAT) (con't)				Use Group: INDOOR FOOD (con't)							
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	SD	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	TX	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	WY	C20, CAL
SHEEP (MEAT)				Use Group: INDOOR FOOD							
Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	013	C20, CAL Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.
	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	MT	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NM	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	SD	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	TX	C20, CAL
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	WY	C20, CAL
NON-FOOD/NON-FEED											
GOATS (WOOL/ANGORA ANIMAL)				Use Group: INDOOR NON-FOOD							

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. # Apps Tex. @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

GOATS (WOOL/ANGORA ANIMAL) (con't) — Use Group: INDOOR NON-FOOD (con't)

Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	013		C20, CAL	Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.
	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	MT		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	NM		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	SD		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	TX		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	WY		C20, CAL	

SHEEP — Use Group: INDOOR NON-FOOD

Animal treatment (rubber bladder collar)., When needed., Glove.	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	013		C20, CAL	Geo.013: The collar may not be used in the following California counties due to potential adverse effects to endangered species (California condor): Fresno, Kern, Kings, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura. The collar may be used in various counties (see label for specific counties) of the following states: California, Idaho, Michigan, Minnesota, Montana, Washington, Wisconsin, and Wyoming. Written approval, on an annual basis, must be obtained from the U.S. Fish and Wildlife Service Office prior to use in these states.
	FM/L	NA	6.650E-04 lb collar	*	NS	NS	NS	NS	NS	NS	MT		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	NM		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	SD		C20, CAL	
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	TX		C20, CAL	

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
SHEEP (con't)				Use Group: INDOOR NON-FOOD (con't)								
	FM/L	NA	6.708E-04 lb collar	*	NS	NS	NS	NS	NS	NS	WY	C20, CAL

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

FM/L	: FORM NOT IDENTIFIED/LIQUID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C20 : Endangered species restriction.
CAL : Do not contaminate water, food or feed.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

013	: Other
MT	: Montana
NM	: New Mexico

GEOGRAPHIC CODES (Cont.)
SD : South Dakota
TX : Texas
WY : Wyoming

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case SODIUM FLUOROACETATE covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to SODIUM FLUOROACETATE in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols 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. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this 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.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Sodium Fluoroacetate

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	LM	41216101
61-2A	**Start. Mat. & Mnfg. Process**	LM	42127401
61-2B	**Formation of Impurities**	LM	41216101
62-1	**Preliminary Analysis**	LM	41631701
62-2	**Certification of limits**	LM	41631702
62-3	**Analytical Method**	LM	41631704
63-2	**Color**	LM	42678801
63-3	**Physical State**	LM	42678802
63-4	**Odor**	LM	42678803
63-5	**Melting Point**	LM	41171102
63-7	**Density**	LM	41171103
63-10	**Dissociation Constant**	LM	41171102
63-12	**pH**	LM	41171103
63-13	**Stability**	LM	42678804
63-17	**Storage stability**	LM	41631703
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	LM	*
71-2A	**Avian Dietary - Quail**	LM	43210601
71-2B	**Avian Dietary - Duck**	LM	43210602
71-5A	**Simulated Field Study**	LM	41958701
71-5B	**Actual Field Study**	LM	41514901
72-1A	**Fish Toxicity Bluegill**	LM	42961601
72-1C	**Fish Toxicity Rainbow Trout**	LM	42961602
72-2A	**Invertebrate Toxicity**	LM	42961603
TOXICOLOGY			
81-1	**Acute Oral Toxicity**	LM	40016971, 65627, *
81-2	**Acute Dermal Toxicity**	LM	152129
81-3	**Acute Inhalation Toxicity**	LM	Waived
81-4	**Primary Eye Irritation - Rabbit**	LM	40402603

Data Supporting Guideline Requirements for the Reregistration of Sodium Fluoroacetate

REQUIREMENT		USE PATTERN	CITATION(S)
81-5	**Primary Dermal Irritation - Rabbit**	LM	40402604
81-6	**Dermal Sensitization**	LM	Waived
82-1(a)	**90-Day Feeding - Rodent**	LM	40016990, *
85-1	**General Metabolism**	LM	*
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	LM	61751, 40016958, 40016959

*See Appendix C, Bibliography for citations from the published literature

GUIDE TO APPENDIX C

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" 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 identifying 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 standard of the American National Standards Institute (ANSI), expanded to provide for certain 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:

      (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. 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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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice

Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend

deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a

completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be

bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable

toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the 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 PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final

report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SODIUM FLUOROACETATE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of SODIUM FLUOROACETATE. 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 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this sodium fluoroacetate Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Leonard Ryan at (703) 308-8067.

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

Leonard Ryan, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: SODIUM FLUOROACETATE

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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.

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

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

Item 4. The guidelines 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 patters (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. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on 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 my 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 require 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 upgrade (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) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant'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 require 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 chosen. I also understand that the deadline for submission of data as specified by the original data cal-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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF SODIUM FLUOROACETATE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing sodium fluoroacetate as the active ingredient, 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.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, 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 own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she 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, he/she 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. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

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 he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she 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, he/she 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 his/her studies and offering to cost share (Option 3) those studies.

Seven products were found which contain sodium fluoroacetate as the active ingredient. The products have been placed into one batch and a "no batch" category in accordance with

the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in the batch. Table 2 lists the product which has been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	13808-7	1.0	Liquid
	35975-4	1.0	Liquid
	35978-8	1.0	Liquid
	39508-2	1.0	Liquid
	46779-1	1.0	Liquid
	56228-22	1.0	Liquid

The following table lists a product that was either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrant of this product is responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
56228-26	90.0	Solid

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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 suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Sodium fluoroacetate RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

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