REREGISTRATION ELIGIBILITY DOCUMENT

WARFARIN AND ITS SODIUM SALT

LIST A

MAY 1991

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

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EXECUTIVE SUMMARY

Warfarin and its sodium salt are rodenticides registered in the United States to control commensal rodents in domestic dwellings (indoor and out), animal premises, agricultural premises and equipment, commercial and industrial sites. The predominant formulations are warfarin baits which are dry (meal, pelleted, paraffinized); and a 1.0% dust for use as a tracking powder; and the sodium salt formulations diluted with water to make liquid baits.

A Registration Standard for warfarin and its sodium salt was issued in August 1981. The Registration Standard summarized the available data supporting the registration of warfarin and its sodium salt and required additional data to assure that the proper use of the pesticide posed no potential adverse effects to man or the environment.

In 1989, the Agency completed a review of the warfarin data base including the data submitted in response to the 1981 Registration Standard and issued a "Draft Warfarin Reregistration Document" for public comment. The Agency found that it had sufficient information on the health effects of warfarin and on its potential for causing adverse effects to the environment to conclude that few additional studies were needed to characterize the risk of warfarin or its sodium salt. The "Draft" document was never issued in final because it has been superseded by the current Reregistration Eligibility Document.

The Agency has determined that all uses of warfarin and its salt will not cause unreasonable risk to man or the environment and are eligible for reregistration. However, the Agency is requiring product chemistry data, and fish and aquatic invertebrate data on the sodium salt. The product chemistry data are being required to replace unacceptable studies. The fish and aquatic invertebrate data are being required in order to conduct a complete risk assessment for the sodium salt. Because of the sodium salt use patterns (i.e. use only in and around buildings) the Agency believes there is little possibility for aquatic organism exposure and the sodium salt can be reregistered at this time. Warfarin data cannot be used as a substitute for the sodium salt data because of significant differences in solubility between the two compounds.

Because tracking powder uses in food and feed handling establishments are now considered to be food uses, registrants will have to adopt labeling language limiting the placement of tracking powder to inaccessible areas in order to be eligible for reregistration. If registrants do not adopt the restrictive

label language specified in this document, they will be required to develop residue chemistry data and possibly establish tolerances.

Before reregistering each product, the Agency is requiring that product specific data and revised labeling be submitted within 8 months of the issuance of this document. In an effort to reduce time, resources, and number of animals needed to fulfill the acute toxicology data requirements for warfarin containing end use products, the Agency has "batched" products considered to be similar with respect to acute toxicity testing requirements. After reviewing these data and the revised labels, the Agency will determine whether to reregister a product based on whether or not that product meets the requirements in Section 3 (c)(5) of FIFRA. End use products containing warfarin in combination with other active ingredients will not be reregistered until the Reregistration Eligibility Documents for all active ingredients contained in that product are issued. However, product specific data for these products are being called in at this time.

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
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 or feed, e.g., mg/l or ppm.
LC_{50} 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.,m mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPT	Maximum Permissible Intake

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

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 9 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 of warfarin and its sodium salt. The document consists of six sections. Section I is this introduction. Section II describes warfarin and its sodium salt, its uses and regulatory history. Section III discusses the human health and environment assessment based on the data available to the Agency. Section IV discusses the reregistration decision for warfarin and its sodium salt. Section V discusses the (the) reregistration requirements for Warfarin and its sodium salt. Section VI is the Appendices which support this reregistration eligibily document. Additional details concerning the Agency's review of available data are available on request.[1]

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[1]EPA's reviews of data on the set of registered uses considered for EPA's analyses may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION DECISION DOCUMENT

A. Identification of Active Ingredient

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

Common Name: Warfarin and its sodium salt

Chemical Name: 3-(alpha-acetonylbenzyl)-4-hydroxycoumarin

Chemical Family: Coumarin anticoagulants

CAS Registry Number: 81-81-2

Office of Pesticide Programs Chemical Code Number:
086002 (warfarin)
086003 (sodium salt of warfarin)

Empirical Formula: $C_{19}H_{16}O_4$
$C_{19}H_{15}NaO_4$ (sodium salt of warfarin)

Trade Names: Warfarin, Coumarin, Coumafene, Co-Rax, Cov-R-Tox, Kypfarin, Liqua-Tox, Rodex, Rax, Rodex Blox, Tox-Hid

Physical Characteristics: The following information is on technical warfarin unless otherwise indicated.

Molecular Weight: 308.4
330.1 (sodium salt of warfarin)

Color: White powder or crystal

Odor: None

Melting Point: 159 to 165 ½C

Solubility: 0.196 mg/mL water at 25 ½C, up to 8% in acetone, up to 2% in ethanol. The sodium salt formulation is readily soluble in water.

Dissociation Constant: pKa - 4.9

Octanol/Water Partition Coefficient: Log K_{ow} = 2.37

pH: 7.2 to 8.3 in water

Stability: Stable under normal conditions

Corrosion Characteristics: Non-corrosive

B. Use Profile

Type of Pesticide: Rodenticide

Mechanism of Action: Blood anticoagulant that leads to internal bleeding and hemorrhaging.

Use Sites: Domestic dwellings (indoor and out), animal premises (cattle feed lots, stockyards, poultry houses), agricultural premises and equipment, commercial and industrial sites (including food processing, handling and storage areas, meat and poultry processing plants).

Pests: Baits for commensal rodents. Commensal rodents are species which live in close association with humans and obtain much of their diets from human food. In the United States, commensal rodents include the Norway rat (Rattus norvegicus), roof rat (Rattus rattus), and house mouse (Mus musculus).

Formulation Types Registered:

Warfarin: 0.3, 0.4, 0.5, and 2 percent concentrates for preparing dry baits; 0.025 to 0.054 percent ready-to-use meal, pelleted, or paraffinized baits; 1.0 percent dust for use as a tracking powder. Concentrates to be diluted with bait materials at rates of 12 to 79 parts bait to 1 part concentrate to yield solid baits that are 0.025 percent warfarin.

Sodium Salt of Warfarin: 0.0127 to 0.54 percent salt formulations to be diluted with water to make 0.005 percent sodium salt of warfarin liquid bait solutions; 0.54 percent liquid concentrates to be diluted with water to make 0.025 percent sodium salt of warfarin liquid baits.

Methods and Rates of Application:

Solid Baits: Individual bait placements of 1/4 to 2 ounces (or equivalent) for house mice, spaced at intervals of 8 to 12 feet; individual bait placements of 3 to 16 ounces for Norway rats and roof rats. Baits are to be protected by tamper-resistant bait stations when applied in sites

accessible to children, pets, domestic animals, and nontarget wildlife.

Liquid Baits: Individual placements in chick founts or other suitable liquid dispensers or in covered bait stations adapted for containing and dispensing liquid baits. At least 1 pint of bait is used per placement for Norway rats and roof rats and 4 to 8 ounces for house mice. Baits applied in areas accessible to children, pets, domestic animals, and nontarget wildlife are to be protected by tamper-resistant bait stations adapted for confining and dispensing liquid baits.

Tracking Powders: For dusting of burrows or small patches of indoor surfaces; treatment rates are 1 ounce dust per 2.5 square feet of runway area for house mice and 2 ounces per 2.5 square feet of runway for rats. These products are to be used only in areas not accessible to children, pets, domestic animals, and nontarget wildlife.

C. Regulatory History

Warfarin and its sodium salt were Federally registered in 1952 for use as a rodenticide. A Registration Standard for warfarin and its sodium salt was issued in August 1981. That document identified unfilled data requirements in product chemistry, acute toxicity, ecological effects, and product efficacy that were necessary for reregistration. This document reflects a reassessment of all data submitted in response to the registration standard and used to support the reregistration of warfarin and its sodium salt.

A copy of the Registration Standard can be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, under the NTIS Stock No. PB 82-140716.

The Agency issued a "Draft Warfarin Reregistration Document" in April 1989. Notice of availability of the document was published in the FEDERAL REGISTER May 10, 1989 (54 FR 20197). Comments were received from three persons. Copies of those comments and the Agency's response are available from EPA's Freedom of Information Office, 401 M Street SW., Washington, DC 20460, Mailcode: H7502C.

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

This section discusses the Agency's assessment of the scientific data base of warfarin and its sodium salt for purposes of determining the reregistration eligibility for the subject pesticide. The reregistration decision and supporting regulatory position and rationales are contained in Section IV.

A. Human Health Assessment

1. Toxicology Data Base

This section discusses data available to the Agency for the toxicological evaluation of warfarin and and its sodium salt. All generic toxicology data requirements are satisfied.

Warfarin, a synthetic analogue of Vitamin K, functions as an antivitamin. Warfarin is a member of the coumarin family of chemicals of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of humans with hypercoagulation problems. The toxicity, mechanism of action, and treatment of overdoses of warfarin are part of the basic training of physicians. The Agency has based its determinations relative to human safety in this document on this body of human evidence and experience.

There is a delay of 12 to 72 hours between the ingestion of a single toxic dose of warfarin and the appearance of the toxic effects (hypocoagulation). The length of this delay is dependent on the normal half-life of the Vitamin K-dependent coagulation factors and is not significantly decreased by administering larger doses of warfarin. The mechanism of action explains the occurrence of toxic effects from daily ingestion of small doses of warfarin.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the Vitamin K-dependent clotting factors, II, VII, IX, and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematoses, uterine bleeding in women, epistaxis, and gingival bleeding. Death follows excessive external or internal bleeding.

The high toxicity of technical warfarin clearly places it in Toxicity Category I. Because of the physical chemistry of warfarin, dermal and inhalation toxicity are not significant. Human experience with administration of warfarin by both oral and injection routes has produced no reports of allergic or sensitization problems.

Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy. Coumarin derivative use or abuse in pregnant women results in one-sixth of pregnancies ending in abortion or stillbirth. As stated previously, warfarin's toxicity, and mechanism of action in humans are well established. But the concentration of warfarin contained in bait material in products registered for homeowner use is low (0.025 to 1.0% active ingredient). Therefore, there is little potential for human toxicity from a single ingestion of treated bait from these products. Based on the availability and completeness of human information and the registered use patterns of warfarin, additional toxicology studies are not required.

Many incidents or suspected incidents of human exposure to anticoagulant rodenticides are reported annually to poison control centers. However, accidental ingestions of warfarin seldom result in life-threatening or disabling symptoms that can be attributed directly to warfarin, and there does not appear to be any evidence of significant health effects from single ingestions of warfarin.

The exact number of annual pet exposure incidents or suspected incidents that result from the use of warfarin against commensal rodents is unknown but many incidents are reported annually. Dog incidents account for most of the reported nontarget animal exposures. Deaths occur in some pet exposure incidents involving warfarin.

These reported human and pet poisoning incidents point to the need to require tamper-resistant bait stations when baits are applied in areas accessible to children and nontarget animals. Warfarin's use patterns do not trigger the data requirements for applicator or reentry exposure studies.

2. Dietary Exposure

Currently, there are no tolerances or exemptions from the requirement of tolerances for residues of warfarin in or on food/feed items. When the Registration Standard for warfarin was issued in August 1981, no residue chemistry data were required because none of the Federally registered uses was regarded as a food/feed use. Since that time the guidelines for residue chemistry have been issued. The Agency has subsequently determined that the use of tracking powder formulations in agricultural premises and in commercial, industrial, and institutional sites have the potential to contaminate food/feed products from rodents, insects and human tracking residues from treated areas.

The registrants of tracking powder formulations are required either to place additional use restrictions on their product labeling to reduce the likelihood of food or feed contamination, or to develop data to demonstrate whether warfarin can contaminate food/feed products from the currently registered use (refer to the residue chemistry data requirement tables). If a registrant elects to retain the current label with no additional restrictions and the required residue data confirm that warfarin can be transferred to food/feed products, appropriate food/feed additive regulations, supported by a full complement of toxicology and residue chemistry data, will be required. These data requirements can be avoided by the registrants of tracking powders if their product labels are modified to limit the use of tracking powders to areas where food contamination is unlikely.

There are no Codex Maximum Residue Levels for residues of warfarin in or on food/feed items.

3. Product Chemistry

Since the issuance of the 1981 Standard, certain product-specific chemistry data have been submitted to the Agency. Further data are still required. These data are specifically identified in Appendix D.

B. Environmental Assessment

This section discusses the data available for assessing the environmental impact of warfarin and its sodium salt. All previously required data have been submitted and found acceptable except for Guidelines 72-1a and b (fish toxicity - bluegill sunfish and

rainbow trout) and 72-2 (invertebrate toxicity) using the sodium salt. Because of differences in solubility between warfarin and warfarin sodium salt, fish and invertebrate toxicity studies with the sodium salt are required in addition to the existing data for warfarin. The absence of these studies will not adversely affect the reregistration eligibility of warfarin and its sodium salt since the Agency does not expect significant exposure to occur in the aquatic environment from the currently registered uses (indoor and near buildings). However, these ecological effects data are still needed to confirm the Agency's expectation that no unacceptable risk will be posed to fish and aquatic invertebrates.

1. Environmental Fate Assessment

Based on the registered use patterns of warfarin, it is anticipated that there is insignificant environmental exposure from the chemical. As warfarin is not applied as a ground spray or aerially, it does not trigger any spray drift data requirements.

Groundwater Concerns

Relatively little environmental exposure of warfarin baits is expected when the chemical is used according to label directions. No groundwater monitoring data have been required.

2. Ecological Effects Assessment

Avian Studies

An acute study on bobwhite quail showed that warfarin has an LD_{50} > 2000 mg/kg. There is sufficient information to characterize warfarin as practically nontoxic to game birds.

In subacute dietary tests, warfarin was found to be moderately toxic to practically nontoxic to upland game birds (LC_{50} of 625 ppm and 6690 ppm with bobwhite quail). In waterfowl, warfarin was also found to be moderately toxic to practically nontoxic (LC_{50} of 890 ppm and > 5000 ppm with mallard ducks). While these studies show variability, the Agency concludes that use of warfarin end-use products according to current use directions and restrictions would preclude significant exposures of wild avian species to warfarin. Therefore, no additional testing for warfarin or its sodium salt is required.

Aquatic Studies

Studies have been submitted showing the LC_{50} values for Daphnia magna, bluegill sunfish and rainbow trout. However, the LC_{50}'s greatly exceed the established solubility of warfarin in water. The solubility of warfarin, which varies with water temperature, was reported to be 17 ppm in the Daphnia study, 16 ppm in the trout study and 17.5 ppm in the bluegill study. Thus, the Agency is considering the LC_{50} values for purposes of risk assessment to be the limits of solubility. At its maximum concentration in water, warfarin is not known to be toxic or only slightly toxic to fish.

The Agency is not requiring a repeat of the warfarin aquatic tests, even though certain questions remain, because of the nonaquatic use pattern, the insolubility of warfarin, and long field experience that has not shown any potential for hazards to aquatic organisms.

Studies are being required to assess the toxicity of the sodium salt of warfarin since it is more soluble than warfarin in water. However, the sodium salt of warfarin is eligible for reregistration, even while these data are being developed, since significant exposure is not expected to occur from currently registered uses.

Secondary Poisoning Hazards

Most applications of warfarin are made under the following use patterns: terrestrial non-food crop (commercial, institutional, industrial premises/ equipment); residential outdoor (household/domestic dwellings); indoor non-food (farm/barns, poultry and rabbit houses, food/meat processing plant premises/ equipment, food distribution/storage facilities); and indoor residential (household/domestic dwellings, veterinary premises). In addition, warfarin baits are placed directly at a site, i.e. not broadcast, sprayed or applied aerially, which greatly limits the potential for any secondary exposure.

Secondary exposure is considered to be low because the levels of warfarin in the target animals are generally too low to be toxic to either a predator or scavenger except under the most extreme conditions. A predator or scavenger would have to consume poisoned target animals for several consecutive days before it

would be poisoned itself.

Endangered Species Concerns

Because of warfarin's established, high mammalian toxicity and because of its use patterns, the Agency has identified warfarin as having the potential to affect endangered and/or threatened mammals adversely. Therefore, it is in need of further evaluation. Requirements, if any, to preclude harm to listed mammals will be addressed in a forthcoming, formal consultation with the U. S. Fish and Wildlife Service.

IV. REREGISTRATION DECISION FOR WARFARIN AND ITS SODIUM SALT

A. Determinations of Eligibility for Reregistration

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

The data identified in Appendix A were sufficient to allow the Agency to conduct a reasonable risk assessment for all registered uses of warfarin and its sodium salt and to determine for all such uses that warfarin and its sodium salt can be used without resulting in unreasonable adverse effects on the environment. The Agency finds that all products which contain warfarin and its sodium salt as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V. of this document ("Product Reregistration").

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,

and the data identified in Appendix A. Although the Agency has found that products containing warfarin and its sodium salt 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 registration of products containing warfarin and its sodium salt if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

The following is a summary of the regulatory positions and rationales for warfarin and its sodium salt. Where label revisions are imposed, specific language is set forth in the labeling sections IV.C. and V.C. of this document.

1. Eligibility for Reregistration

The Agency finds that it has sufficient information on the health effects of warfarin and its sodium salt and on their potential for causing adverse effects to fish and wildlife and the environment to conclude that products containing warfarin and its sodium salt are eligible for reregistration. Only certain product chemistry and three acute aquatic toxicity studies on the salt are still needed. Tracking powders used in food/feed handling establishments are eligible for reregistration provided the registrant(s) adopt the restrictive labeling language required in the RED.

Rationale

The Agency has reviewed all available data supporting the registration of products that contain warfarin. This review shows that additional data are not needed to support most registered uses of this chemical. The Agency finds that additional toxicity data on fish and invertebrates are needed for the sodium salt of warfarin due to the differences in solubility between warfarin and the sodium salt. Because tracking powder uses are now considered to be potential food uses, data are required to determine whether tolerances must be established under section 408 or 409 of the Food, Drug, and Cosmetic Act unless the restrictive labeling cited in section V is adopted. The Agency has determined that warfarin products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks of adverse effects to man and the environment.

2. Food Use Restrictions

The Agency is requiring additional use restrictions on the label or submission of residue chemistry data to support use of the 1 percent dust tracking powder formulation in agricultural premises and food handling establishments.

3. Restricted Use

The Agency is continuing to require that warfarin tracking powder end-use products be classified as Restricted Use pesticides.

Rationale

The use pattern of this formulation, its higher toxicant levels (in relation to baits), the need for special training and application equipment, and the potential for misapplication by users require this Restricted Use status.

Rationale

Due to the nature of the formulation and its method of application (patches of dust), the Agency has determined the current use restrictions are not adequate to alleviate concern that contamination of feed stored in agricultural buildings or food in food handling establishments may result from the use of tracking powder in these facilities. Examples of potential avenues of food contamination include: 1) tracking of residues from treated areas by rodents, insects, or humans; 2) distribution of particulate matter through forced air ventilation systems; and 3) routine floor cleaning or cleaning specifically to remove old or excess tracking powder. Registrants may avoid the requirement to conduct residue chemistry testing by amending their product registrations to limit the use of tracking powder to areas where food contamination is unlikely. Placement of tracking powders would be limited to concealed inaccessible places such as those between floors and walls. Application of tracking powders along walls, in corners, in open floor ares or on rafters of rooms in which feed or food is handled or stored is prohibited. The Agency believes these measures will significantly reduce the potential for food/feed contamination and will eliminate thte need for residue data. An acceptable label statement for this purpose is found in Section V, subsection D, item 2.

4. Bait Station Requirement

The Agency will require expansion of label statements regarding the use of protective bait stations.

Rationale

Many nontarget exposures of humans and nontarget animals to anticoagulant rodenticides are reported each year. EPA believes that most accidental exposure incidents could have been prevented if products had been used, stored, and handled according to label directions. The Agency is currently preparing a PR Notice describing criteria and requirements for tamper-resistant bait stations. When completed, this notice will be sent to all appropriate registrants. The use of tamper-resistant bait stations is required when baits are applied in areas accessible to children and nontarget animals.

5. Teratology Warning

The Agency is requiring placement of a teratology warning statement on the labels of manufacturing-use products and warfarin concentrates used for preparing dry baits. Refer to Section IV, subsection C.

Rationale

High doses of warfarin are known to cause teratogenic effects in humans. The 1981 registration standard required placement of a teratogen warning on the labels of manufacturing-use products. The warning statement is being changed to be more explicit about this hazard. The warning is required of manufacturing-use products because workers may receive significant doses of warfarin when handling these products. This warning statement is also required on labels of certain end-use products (concentrates used for preparing baits).

6. Format Labels

Labels with special formats should be used for dry concentrate, sodium salt concentrate, and ready-to-use dry bait products which are used to control Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures.

The formats for the labels are given in Appendix D, Attachment D.

Rationale

Because of the limited use patterns, the high number of products, and the Agency's extensive experience with reviewing labels and efficacy data on these types of products, these format labels provide an efficient way to achieve consistent, acceptable labeling.

7. Batching of Warfarin End-Use Products

The Agency has batched warfarin end-use products to meet the acute toxicity data requirements for reregistration.

Rationale

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of the end-use products containing the active ingredient, warfarin, 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 and labeling (e.g., signal word, use classification, precautionary labeling). 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.

8. Efficacy Data Requirements

The Agency is continuing to require the submission of efficacy data for manufacturing-use and end-use products.

Rationale

The pests which warfarin controls are significant vectors of diseases of public health concern. The effectiveness of the products is influenced not only by the amount of the active ingredient, but also by the quality of the active ingredient and the flavor of the bait ingredients in a product.

Further, inert ingredients vary considerably from one product formulation to another. Therefore, efficacy data will continue to be required to ensure that all registered warfarin products are effective against commensal rodents. Refer to Appendix D for additional information on these testing requirements.

9. Label Amendment Requirements

Registrants of products used for control of additional pests or at different sites than those covered on the labels prescribed in Section V, subsection C (part 1-5) must submit labeling for the species, sites and application rates, and method for the product.

Rationale

The Agency must assess the labeling for such products to determine whether the use is consistent with FIFRA and other applicable statutes.

B. Additional Generic Data Requirements

The generic data base supporting the reregistration of products containing warfarin and its sodium salt has been reviewed and determined to be substantially complete. The remaining generic data that must be submitted are certain product chemistry data, three acute toxicity tests on bluegill sunfish, rainbow trout, and freshwater invertebrates using the sodium salt formulation. Residue data from the tracking powder use in food/feed handling establishments is required unless the registrant(s) adopt the restrictive labeling cited in this document which limits placement of tracking powders to inaccessible locations. Refer to Appendix D for additional information on the generic data requirements for warfarin and its sodium salt.

C. Labeling Requirements for Manufacturing-Use Products Containing Warfarin and Its Sodium Salt

All products are required to bear appropriate labeling as specified in 40 CFR 156.10. Specific information regarding label requirements is included in the Pesticide Reregistration Handbook.

All warfarin manufacturing-use product labels must bear the following statements:

a. "For formulation only into registered end-use

rodenticides used in and around buildings, similar man-made structures, and in transport vehicles."

b. "Exposure to warfarin or [sodium salt] during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects." [Place in Hazards to Humans and Domestic Animals" section of the label.]

c. "Use a dust respirator" [If the product is a respirable dust]. "Use rubber gloves when mixing baits containing warfarin".

V. PRODUCT REREGISTRATION

Based on the reviews of the generic data for the a.i. warfarin and its sodium salt, all products containing these active ingredients are eligible for reregistration.

A. Determination of Eligibility

All products currently registered containing the active ingredient warfarin and its sodium salt are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data and determine whether to reregister in-dividual products.

B. Existing Stock Requirements

Registrants of warfarin products are permitted to sell or distribute products bearing old labeling (or composition or packaging) for 26 months after the issuance of the RED. The issuance date is the stamped date on the RED cover letter to the registrants.

Persons other than registrants are permitted to sell or distribute warfarin products bearing old labeling for an additional 24 months, or 50 months from the issuance date of the RED. The 26 month time frame is composed of eight months for submission of labeling to the Agency, six months for Agency review and approval of labeling and one year of sales and distribution following the six months allowed for Agency approval.

C. Product-Specific Data Requirements

The product-specific data were called in August 1981 when the Warfarin and its Sodium Salt Registration Standard was issued.

Registrants must review previous data submissions to ensure that they meet current standards (see Appendix D, Attachment F - EPA Acceptance Criteria) and if not, commit to conduct new studies. If the registrant believes that previously submitted data meet current testing standards, then he should cite the MRID numbers of these studies following the instructions in the Requirement Status and Registrants Response form provided for each product.

D. Labeling Requirements for End-Use Products Containing Warfarin and Its Sodium Salt

All products are to bear appropriate labeling as specified in 40 CFR 156.10. Specific information regarding label requirements is included in the Pesticide Reregistration Handbook.

1. Required Statement on Labels of Tracking Powder and Concentrates Used To Prepare Dry Baits

"Exposure to warfarin during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects." [Place in Hazards to Humans and Domestic Animals" section of the label.]

2. Required Statements for Labels for Tracking Powders with End-Use Directions

a."Restricted Use Pesticide"

For retail sale to and use only by certified applicator or persons under their direct

supervision and only for those uses covered by the certified applicator's certification. [Place in the box on top of the front panel of the label.]

b. "This rodenticide is lethal to warm-blooded animals." [Place in "Precautionary Statements" section of label.]

c. "Tracking powder must be placed in locations not accessible to children, pets, domestic animals, or nontarget wildlife. If using this product in agricultural buildings where livestock feeds are stored, or in commercial food service, food manufacturing or food processing establishments, limit treatments to concealed, inaccessible places such as spaces between floors and walls. Do not apply tracking powder along walls, in corners, in open floor areas, or on rafters of rooms in which food or feed is handled or stored." [Place in "Use Restrictions" portion of the "Directions for Use" section of label.]

A sample label has been developed for these products (refer to Section VI, Appendix D, Data Call-In, Attachment D, Format Label D-1).

3. Required Statements for Labels for Concentrates with Directions for Mixing and Applying Warfarin or Sodium Salt of Warfarin Baits and Ready-to-Use Warfarin Baits (Loose Baits)

Sample labels (refer to Appendix D, Attachment D, Format Label, D-2 and D-3) have been developed for these types of products. The texts of these labels are formatted to reflect language required for these types of warfarin products at the time that this document was issued as well as other required language.

Required texts include all of the material in the following portions of the formated labels: "KEEP OUT OF REACH OF CHILDREN," "CAUTION," "READ THIS LABEL," "IMPORTANT," "PRECAUTIONARY STATEMENTS," "ENVIRONMENTAL HAZARDS," and "STORAGE AND DISPOSAL" (for "household" products).

While the text in the other portions of the label may vary, the organizational format for the "center panel" (or "front panel," for a box) is required.

"STORAGE AND DISPOSAL" statements for "Non-household Products" may vary only within the requirements for PR Notice 83-3. "MIXING DIRECTIONS" necessarily will vary according to the concentration of warfarin in the product, the composition of the bait that was tested, and other factors.

Texts of "USE RESTRICTIONS," "SELECTION OF TREATMENT AREAS," "APPLICATION DIRECTIONS" (including "RATS:," "MICE:," and "RATS/MICE:" are strongly suggested. Registrants may not depart substantially from these texts. Requests to add new use sites to the label may elicit additional requirements for ecological effects data.

4. Required Statements for Labels for Ready-to-Use Warfarin Baits with Nonprotective Subpacking

These products are ready-to-use dry baits subpackaged in plastic or paper packets ("place packs," "bait trays," etc.) that are to be used as measured bait placements for at least one target species claimed on the product label. Labeling for the outer container for such products must follow the format for "loose" ready-to-use dry warfarin baits except that "APPLICATION DIRECTIONS" for baiting rats with place packs (or trays) should be expressed in terms of numbers of subpackaging units to use rather than as ounces of bait per placement. If subpackaging units are larger than 2 oz, instructions for baiting house mice should require that packs be opened and that appropriate amounts of bait be used (i.e., 1/4 to 1/2 oz for most placements and up to 2 oz at locations of extremely high mouse activity).

Labels for the packs or trays themselves must include all information on the label of the outer package except for the "DIRECTIONS FOR USE," which may be abridged as follows:

"DIRECTIONS FOR USE"

"It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label on the outer package before using this product. It is illegal to sell these place packs [or bait trays, if more accurate] individually. "

5. Required Statements for Labels for "Weather-Resistant" Ready-to-Use Warfarin Baits

Warfarin baits claimed to be effective when used in wet or damp areas must be evaluated in efficacy tests with fresh and "weathered" baits. EPA's protocols 1.213 and 1.214 describe procedures for "weathering" baits. Labels for these products should follow the outline in the format label for ready-to-use warfarin baits, with appropriate adjustments to "USE RESTRICTIONS" for the various wet and damp use sites. "APPLICATION DIRECTIONS" may have to be modified to account for large or atypical bait forms (e.g., paraffinized blocks).

The EPA protocols 1.213 and 1.214 should be obtained from Product Manager 16 of the Registration Division [H7504C].

APPENDIX A

Generic Data Requirements for Reregistration of Warfarin and its Sodium Salt and Data Citations Supporting Reregistration

GUIDE TO APPENDIX A

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

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

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

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

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. The following letter designations are used for the given use patterns:

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

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

3. Bibliographic citation (Column 3). If the 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 Appendices for a complete citation of the study.

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	N/A
61-2(a)	Beginning Materials & Manufacturing Process	all	N/A
61-2(b)	Discussion of Impurities	all	N/A
62-2	Certification of Limits	all	N/A
62-3	Analytical Method	all	00002438
63-2	Color	all	00002438
63-3	Physical State	all	00002438
63-4	Odor	all	00002438
63-5	Melting Point	all	00002438, 00163111, 00133948, 00002387
63-6	Boiling Point	all	N/A

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)
PRODUCT CHEMISTRY (Continued)			
63-7	Density	all	N/A
63-8	Solubility	all	00002438
63-9	Vapor Pressure	all	N/A
63-10	Dissociation Constant	all	00133948
63-11	Octanol/Water Partition Coefficient	all	00142539
63-12	pH	all	00002438

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)

TOXICOLOGY

o The toxicology of warfarin, its mechanism of action and treatment of overdose in humans are well established. Based on the available human information, animal toxicity studies in warfarin are not required. Thus, the toxicological tests which are normally required for pesticides under the existing warfarin use pattern are waived.

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)

ENVIRONMENTAL FATE

The environmental fate data requirements are waived since the use pattern and label recommendation of these pesticides indicate that significant residues of concern are not expected to be introduced into the environment. The two spray drift requirements, droplet size spectrum and drift field evaluation, are not applicable because warfarin and its sodium salt are not applied by aerial or ground sprays.

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID, DOCUMENT NUMBER)
ECOLOGICAL EFFECTS			
71-1	Acute Avian Oral - Quail/Duck	C,K,H,I,M	00117979,00156284 00153369,00153366 00156285,00157812
71-2(a)	Acute Avian Dietary - Quail	C,K,H,I,M	00156283
71-2(b)	Acute Avian Dietary - Duck	C,K,H,I,M	00153366, 00156285,00157812[1]
71-3	Wild Mammal Toxicity	C,K,H,I,M	00002469
71-4	Avian Reproduction	N/A	N/A
71-5	Simulated and Actual Field Testing with Mammals and Birds	N/A	N/A
72-1(a)	Fish Toxicity - Bluegill (WARFARIN)	C,K,H,I,M	00117976[1],00153363 00156287
72-1(b)	Fish Toxicity - Bluegill - TEP (WARFARIN)	N/A	N/A

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)
ECOLOGICAL EFFECTS (Continued)			
72-1(c)	Fish Toxicity - Rainbow Trout (WARFARIN)	G,K,H,I,M	00117977[1], 00153364 00156286
72-1(d)	Fish Toxicity - Rainbow Trout-TEP (HP LaserJet Series II (Additional)	N/A HLSEIIAD.PRS%P .	N/A
72-2(b)	Invertebrate Toxicity - TEP	N/A	N/A
72-3	Acute LC_{50} for Estuarine and Marine Organisms	N/A	N/A
72-4	Fish Early Life Stage and Aquatic Invertebrate Life Cycle	N/A	N/A
72-5	Fish Life Cycle	N/A	N/A
72-6	Aquatic Organism Accumulation	N/A	N/A

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)
ECOLOGICAL EFFECTS (Continued)			
72-7	Simulated or Actual Field Testing	N/A	N/A

[1] The percent active ingredient was not given.
[2] These LC_{50}s are greater than the known solubility of warfarin (Snyder, 1953 in Turner, 1987). The study will meet guideline requirements if the LC_{50}s are reduced to the solubility of warfarin in water.

The nontarget area phytoxicity and nontarget insect testing data are not required under the existing use patterns.

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID. DOCUMENT NUMBER)
NON-DIETARY EXPOSURE			
Based on the existing use pattern and lack of toxicological concerns, the non-dietary exposure requirements are waived.			

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF WARFARIN AND ITS SODIUM SALT

AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERN	BIBLIOGRAPHIC CITATION (EPA MASTER RECORD ID, DOCUMENT NUMBER)
RESIDUE CHEMISTRY			
171-4	Magnitude of Residue in Food Handling	L	

If the registrant accepts the label restrictions specified in this document, residue chemistry data are not required. However if the registrant does not adapt the restrictions then the data identified in the Requirements Status and Registrant Response Form are required.

APPENDIX B

WARFARIN AND ITS SODIUM SALT BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX B

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

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

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

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

a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

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

c. Title. In some cases, it has been necessary for 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, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

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

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

MRID CITATION

00002354 Florent M.L. Schruvers (1971) Dicusat--Techn. Grade. (Unpublished study received Oct 13, 1971 under 6720-171; prepared by Chemosweb AB, a subsidiary of Ferrosan--Sweden, submitted by Southern Mill Creek Products Co., Inc., Tampa, Fla.; CDL:102155-A)

00002387 Schering AG (1972) Warfarin Techn.: Specification No. 180: Schering Information. Includes methods dated Apr 6, 1972. (Unpublished study received Apr 26, 1972 under 6900-130; submitted by J.J. Dill Co., Kalamazoo, Mich.; CDL:102157-A)

00002438 Wisconsin Alumni Reserach Foundation (1967) Warfarin Physico-Chemical Specifiications and Analytical Procedures. MAdison, WI: WARF (Also in unpublished submission received Nov. 24, 1975 under 655-543; submitted by Prentis Drug & Chemical Co., Inc., New York, NY; CDL: 231461-R)

00002450 S.B. Penick & Company (19??) Physical Properties of Wa rfcoat 1/1 Encapsulated Warfarin. (Unpublished study received Jun 5, 1974 under 432-535; CDL:022992-A)

00002469 Evans, J.; Ward, A.L. (1967) Secondary Poisoning associated with anticoagulant killed nutria. J. of Am. Vet. Med. Assoc. 151(7): 856-861.

00003281 Wisconsin Alumni Research Foundation (1973) The Coating Process. (Unpublished study received Mar 2, 1973 under 2521-10; CDL:006685-A)

00022551 Chavkin, R.E. (1971) Dicusat Sodium (Warfarin Sodium). (Unpublished study received Jan 1, 1957 under 10442-4; submitted by Biddle Sawyer Corp., New York, N.Y.; CDL:240812-A)

00024140 Biddle Sawyer Corporation (1970) [Dicusat (Techn. Grade)]. (Unpublished study received Jun 2, 1970 under 10442-5; CDL:240752-A)

00055541 Bell Laboratories (1975) Determination of Warfarin by Ultraviolet Spectroscopy: Warfarin EPA-2. Method dated Nov 1975. (Unpublished study received Jun 17, 1980 under 12455-26; CDL:243963-B)

MRID CITATION

00109230 Southern Mill Creek Products Co., Inc. (1982) [Chemistry of Warfarin Concentrate]. (Compilation; unpublished study received Apr 30, 1982 under 6720-53; CDL:247866-A)

00117975 Shapiro, R. (1982) Static Acute Bioassay for the Toxicity of Wincon... to Daphnia magna: Report No. T-2391. (Unpublished study received Sep 3, 1982 under 3282-32; prepared by Nutrition International,Inc., submitted by D-Con Co., Inc. Montvale, NJ; CDL:248782-A)

00117976 Shapiro, R. (1982) Static Acute Bioassay for the Toxicity of Wincon... to Bluegill Sunfish ...: Report No. T-2387. (Unpublished study received Sep 3, 1982 under 3282-32; prepared by Nutrition International, Inc., submitted by D-Con Co., Inc., Montvale, NJ; CDL:248782-B)

00117977 Shapiro, R. (1982) Static Acute Bioassay for the Toxicity of Wincon ... to Rainbow Trout ...: Report No. T-2392. (Unpublished study received Sep 3, 1982 under 3282-32; prepared by Nutrition International, Inc., submitted by D-Con Co., Inc., Montvale, NJ; CDL:248782-C)

00117979 Roth, R.; Shapiro, R. (1982) Avian Dietary LC_{50} Study with Bob White Quail: Report No. T-2402. (Unpublished study received Sep 3, 1982 under 3282-32; prepared by Nutrition International, Inc., submitted by D-Con Co., Inc., Montvale, NJ; CDL:248782-E)

00133948 Biddle Sawyer Corp. (1978) Warfarin, Technical: [Chemistry]. (Compilation; unpublished study received Jul 13, 1978 under 10442-5; CDL:234494-A)

00142539 Opong-Mensah,K.; Porter, W. (19??) n-Octanol-Water Partition Coefficient of Warfarin. Unpublished study received Feb 8,1982; prepared by Univ. of Wisconsin, School of Pharmacy. 27 p.

00143602 Smith, R. (1984) Report of Analysis for Warfarin and Sulfaquinoxaline. Unpublished compilation received Sept 18, 1984; prepared by Motomco, Ltd. 6 p.

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MRID	CITATION
00143603	Smith, R. (1984) Report of Analysis for Warfarin. Unpublished study recieved Sept 18, 1984 prepared by Motomco, Ltd. 6 p.
00146240	Zoecon Industries, Inc. (1977) Product Chemistry Data for Mouse and Rat Bait. Unpublished study received July 5, 1985. 4 p.
00146381	Zoecon Industries, Inc. (1982) Product Chemistry for Starbar SMAX Rat and Mouse Bait Station. Unpublished study received April 28, 1982. 27 p.
00148099	Mohan, G.; Carvel, W.; Dombrowski, L. (1985) Water Solubility of Warfarin Reference to Report No. TP-509-015-05. Unpublished study received May 6, 1985; prepared by Sterling-Winthrop Research Institute. 2 p.
00153363	McAllister, W.; Bowman, J.; Cohle, P. (1985) Acute Toxicity of Technical Warfarin to Bluegill Sunfish (Lepomismacrochirus): Report #33306. Unpublished study received Nov 18, 1985; prepared by Analytical Bio-Chemistry Laboratories, Inc. 54 p.
00153364	McAllister, W.; Bowman, J.; Cohle, P. (1985) Acute Toxicity of Technical Warfarin to Rainbow Trout (Salmo gairdneri): Study No. 33304. Unpublished study received Nov 18, 1985; prepared by Analytical Bio-Chemistry Laboratories, Inc. 55 p.
00153366	Fletcher, D. (1985) 19-Day Dietary LC_{50} Study with Technical Warfarin in Mallard Ducklings: Study No. 85 DC 56. Unpublished study received Nov. 18, 1985; prepared by Bio-Life Associates, Ltd. 41 p.
00153367	Bell Laboratories, Inc. (19??) Product Chemistry of Warfarin. Unpublished study received Nov. 18, 1985; 5 p.

MRID CITATION

00153368 Forbis, A.; Georgie, L.; Burgess, D. (1985) Acute Toxicity of Technical Warfarin to Daphnia magna: Report #33305. Unpublished study received Nov. 18, 1985; prepared by Analytical Bio-Chemistry Laboratories, Inc. 44 p.

00153369 Fletcher, D. (1985) Acute Oral Toxicity Study with Technical Warfarin in Bobwhite Quail: Final Report: Study No. 85 QD 56. Unpublished study received Nov. 18, 1985; prepared by Bio-Life Associates, Ltd. 41 p.

00156283 Beavers, J. (1985) A Dietary LC_{50} Study in the Bobwhite with Warfarin: Final Report: Project No. 205-101. Unpublished study received Feb. 15, 1985; prepared by Wildlife International Ltd. 20 p.

00156284 Beavers, J. (1985) An Acute Oral Toxicity Study in the Bobwhite with Warfarin: Final Report: Project No. 205-103. Unpublished study received Feb. 15, 1985; prepared by Wildlife International Ltd. 16 p.

00156285 Beavers, J. (1985) A Dietary LC_{50} Study in the Mallard with Warfarin: Final Report: Project No. 205-102. Unpublished study received Feb. 15, 1985; prepared by Wildlife International Ltd. 16 p.

00156286 McAllister, W.; Cohle, P. (1984) Acute Toxicity of Warfarin Technical to Rainbow Trout (Salmo gairdneri): Report No. 32461. Unpublished study received Feb. 15, 1985; prepared by Analytical Bio-Chemistry Labs, Inc. 53 p.

00156287 McAllister, W.; Cohle, P. (1984) Acute Toxicity of Warfarin Technical to Bluegill Sunfish (Lepomis macrochirus): Report No. 32460. Unpublished study received Feb. 15, 1985; prepared by Analytical Bio-Chemistry Labs, Inc. 53 p.

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WARFARIN AND ITS SODIUM SALT BIBLIOGRAPHY
REREGISTRATION ELIGIBILITY DOCUMENT

MRID	CITATION

00156288 Forbis, A.; Georgie, L.; Burgess, D. (1984) Acute Toxicity of Warfarin Technical to Daphnia magna: Report No. 32462. Unpublished study received Feb. 15, 1985; prepared by Analytical Bio-Chemistry Labs, Inc. 38 p.

00157812 Shapiro, R. (1986) Avian Dietary LC_{50} Study with Mallard Ducks: Wincon (Warfarin): Report No. T-5513. Unpublished study received Mar. 20, 1986; prepared by Wildlife International, Ltd. 31 p.

00163111 Bell Laboratories Inc. (1986) Analysis for Six Batches of Warfarin and Analytical Methods used. Unpublished compilation received Sept. 8, 1986; 6 p.

00163112 Snyder, J. (1953) Solubilities of Warfarin, Dicumarol, and Cyclocumarol in Water. Unpublished thesis received Sept. 8, 1986; prepared by University of Wisconsin. 10 p.

APPENDIX C

PESTICIDE REREGISTRATION HANDBOOK

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)

Form Approved OMB No 2070-0060 Approval expires 9 30 90

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	b. % by Weight	14 Certified Limits % by Weight a. Upper Limit	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. 2-85) Previous editions are obsolete.

Original and second copy to EPA
Third copy to Applicant

"I UCTIONS TO THE FORM: "CONFIDENTIAL STA NT OF FORMULA"

INSTRUCTIONS

Please Read Carefully Before Completing This Form

The complete chemical composition of each pesticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended

This form is designed for reporting the ingredients used in the formulation of a pesticide product It must be completed and submitted with each application for new registration of a pesticide and application for amended registration if the revision involves a formula change.

Block A — Check the appropriate action for which you are submitting the form

Block B — Number all pages consecutively Enter on each page the total number of pages submitted If more than one page is required, number them "1 of 2," "2 of 3," "3 of 3," etc

1. Name and Address of Applicant/Registrant — Enter the name and address of your firm or authorized agent.

2. Name and Address of Producer — Specify the name of the producer and the address of the site where this product will be produced

3. Product Name — Specify the complete name of this pesticide product as it will appear on the label. This name must be the same as that which appears on the application form.

4. Registration Number/File Symbol — Enter the EPA registration number or file symbol, if known, for this product.

5. EPA Product Manager/Team Number — Enter the name and team number of the EPA Product Manager assigned to this product, if known

6. Country Where Formulated — Specify the country where this product is formulated

7. Weight per Gallon/Bulk Density — For a liquid product specify pounds per gallon of formulated product For a powder or granular product, enter the bulk density of formulated product (as used). Enter weight per unit if the product is produced as a tablet, briquette, or other uniformly shaped product

8. pH — Enter the pH of aqueous formulations and products which are either dispersible or soluble in water. If not applicable enter "N/A."

9. Flash Point/Flame Extension — Specify the flash point as determined by the regulations for pressurized products and/or products known or suspected to burn State the results of the flame extension test for pressurized products including positive flashbacks.

10. Components in Formulation — List as actually introduced into the formulation For each component in your formulation, provide the product name, commonly accepted chemical, the trade name, and the Chemical Abstract (CAS) number for each identifiable ingredient present in that product CAS numbers may be obtained from the Chemical Abstract Service of the American Chemical Society, Columbus, OH For each original and alternate source of each active ingredient in the product, indicate the percent purity of the manufacturing use product, technical product, or other source of active ingredient If one or more components will be obtained from more than one source, enter all alternate sources and all alternate EPA Reg Nos in blocks 10, 11, and 12 or on a separate attachment

ATTENTION: *(Special Instructions for Columns 10, 13, and 14)* Any impurities greater than or equal to 0 1% (or less than 0 1% if the impurity is toxicologically significant) which are associated with the active ingredient(s) of a technical grade (manufacturing or reformulating use) product or an end use product produced by an integrated formulations system should also be listed in column 10 and the corresponding amount, percent by weight, and upper certified limits in columns 13 and 14

11. Supplier Name and Address — Provide the name and address of the supplier of each component in the formulation If one or more components will be obtained from more than one source, specify the names and addresses of the alternate sources also

12. EPA Reg. No. — Specify the EPA registration number, if any, for each active ingredient in the formulation If an unregistered active ingredient is used, have the suppliers submit the chemical specifications, as well as any data required under 40 CFR Part 158

13. Each Component in Formulation —

a. Amount — Specify the quantity of each component as actually introduced into the formulation Units (e g , pounds, grams, gallons, liters) should be expressed as used in the formulation If the quantity is a liquid measure, enter the volume and the specific gravity or the pounds per gallon of the component

b. Percent by Weight — Specify the weight percentage of each component in your formulated product **CHECK YOUR CALCULATIONS**. Note that the weight percentage in many cases will not agree with that shown on the label ingredient statement where the weight percentage of the pure active ingredient(s) must be declared

ATTENTION: PRODUCERS OF MICROBIAL PRODUCTS — *(Special Instructions for Column 13 b)* Please state the percent of active ingredient in British International Units (BIUs), International Toxic Units (ITUs), Polyhedral Inclusion Bodies (PIBs) (viruses), or Colony Forming Units (CFUs) (fungi), as appropriate, and include an equivalent statement of active ingredient per milligram, ounce, pound, etc , of product (e g., a 50% active Bacillus thuringiensis product may have an equivalency value of 1 59 million Aedis aegypti ITU per pound of product)

14. Certified Limits — These limits are to be set based on representative sampling and chemical analysis (i e , quality control) of the product.

a. Upper Limit — Specify the maximum percentage of each active ingredient, intentionally added inert ingredient, and any impurities greater than 0 1%, to be permitted in the product

b. Lower Limit — Specify the minimum percentage of each active ingredient and intentionally added inert ingredient to be permitted in the product.

15. Purpose in Formulation — Specify the purpose of each ingredient both active and inert (For example, disinfectant, herbicide, synergist, surfactant, defoamer, sequestrant, etc) If space is insufficient, abbreviate.

16. Typed Name of Approving Official — Complete this item for identification of individual to be contacted if necessary

17. Total Weight — Specify the total weight of the batch (column 13 a)

18. 21. Complete these items for identification of individual to be contacted if necessary.

APPENDIX D

DATA CALL-IN

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

DATA CALL-IN NOTICE

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain 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 H; or

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment B, (for generic data) and Attachment C (for product specific data), Requirements Status and Registrant's Response Form, (see section III-B); or

3. why you believe EPA should not require your submission of 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 B (generic) and Attachment C (product specific), Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment G).

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 eight 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:

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form and Requirement Status and Registrant's Response form for Generic Data
C - Data Call-In Response Form and Requirements Status and Registrant's Response Form for Product Specific
D - Formatted/Sample Labels
E - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
F - EPA Acceptance Criteria
G - List of Registrants Receiving This Notice
H - Cost Share and Data Compensation Forms for Generic and Product Specific Data, 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. This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient. 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 data required by this Notice are specified in Attachment B (for generic data) and Attachment C (for product specific data), 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 B (for generic data) and Attachment C (for product specific data), Requirements Status and Registrant's Response Form, within the timeframes 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 generic and 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

1. Generic Data

The options for responding to this Notice for generic data are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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 B (for generic data) and Attachment C (for product specific data). The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 A.

a. 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.

b. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 557-2126.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

c. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment B and all

supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

e. Request for Generic Data Waivers. Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 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.

2. Product Specific Data

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

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 B (for generic data) and Attachment C (for product specific data). 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. 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 A.

a. 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 choose 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.

b. 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.2. of this Notice and comprise options 1 through 7 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Document.

d. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose this option, 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

1. Generic Data

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b and/or 7), 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 timeframe (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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or

undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study.
In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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 or protocols. 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 -- 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 -- 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 H. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing 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) " '[r]aw 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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 A. 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 ecological effects studies, the classification generally would be a rating of "core." 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.

2. Product Specific Data

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 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 timeframe (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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2, Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3, Offer to Share in the Cost of Data Development -- The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4, Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5, Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6, Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

a. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii). Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii). Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv). Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v). A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi). A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii). For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii). A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data -- Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply.

You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

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 A, 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 B for generic data and Attachment C for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment A. 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,

Allan S. Abramson, Ph.D.
Acting Director
Special Review and Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form and Requirement Status and Registrant's Response form for Generic Data
C - Data Call-In Response Form and Requirements Status and Registrant's Response Form for Product Specific
D - Formatted/Sample Labels
E - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
F - EPA Acceptance Criteria
G - List of Registrants Receiving This Notice
H - Cost Share and Data Compensation Forms for Generic and Product Specific Data, and Product Specific Data Report Form

ATTACHMENT A

DATA CALL-IN CHEMICAL STATUS SHEET

ATTACHMENT A

WARFARIN & ITS SODIUM SALT: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing warfarin and its sodium salt.

This attachment, the Data Call-In Chemical Status Sheet, contains the reregistration regulatory history of warfarin and its sodium salt, an overview of data required by this notice, and point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, and the Requirements Status and Registrant's Response Form for generic data, (3) Attachment C, the Data Call-In Response Form, and the Requirements Status and Registrant's Response Form for product specific data, (4) Attachment D, Formatted/Sample Labels, (5) Attachment E, EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration, (6) Attachment F, EPA Acceptance Criteria, (7) Attachment G, List of All Registrants sent this Data Call-In Notice, and (8) Attachment H, the Cost Share and Data Compensation Forms for generic and product specific data and Product Specific Data Report Form for use in replying to this Warfarin and its sodium salt Data Call-In. Instructions and guidance accompany each form.

REREGISTRATION HISTORY

In 1981 EPA issued a Registration Standard for warfarin and its sodium salt which summarized the available data supporting its registration and concluded that additional scientific data were needed to fully evaluate the pesticide. Subsequently the Agency reviewed the additional data and revised its scientific and regulatory conclusions in light of the expanded data requirements promulgated in 1984 for registration and reregistration of all pesticides. In April 1989, EPA issued a second Registration Standard in draft for public comment which provided an updated assessment of warfarin and its sodium salt and the data needed to support its continued registration.

DATA REQUIRED BY THIS NOTICE

The Agency has concluded that additional data on product chemistry are needed on warfarin and its sodium salt and fish toxicity studies and an invertebrate toxicity study are needed only on the sodium salt. The Agency has fish and invertebrate toxicity data on warfarin but not on the sodium salt. Because of differences in solubility between warfarin and the sodium salt these ecological effects data are required. The required additional generic data are listed in Attachment B and the required product specific data are listed in Attachment C.

Depending on the results of the studies required in this Notice, as well as those required in the Registration Standard, additional testing may be required.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, please contact:

for the generic data - Herman T. Toma at (703)308 - 8055.
for the product specific data - Robert A. Forrest (703)557 - 2600.

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

Herman T. Toma, Review Manager
Reregistration Branch
Special Review and Reregistration Division H7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

RE: Warfarin and its sodium salt

All written responses to this Notice pertaining to the product specific data requirements should be submitted to:

Robert A. Forrest, Product Manager 14
Insecticide & Rodenticide Branch
Registration Division H7505C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

RE: Warfarin and its sodium salt

ATTACHMENT B

GENERIC DATA CALL-IN RESPONSE FORM
AND
GENERIC REQUIREMENT STATUS AND REGISTRANT'S
RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR
THE DATA CALL-IN RESPONSE FORM

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

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

INSTRUCTIONS

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

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

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

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

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

the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is a end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the

person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

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

DATA CALL-IN RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
003282 D-CON COMPANY INC 225 SUMMIT AVENUE MONTVALE NJ, 07645	0011 Warfarin & its Na salt Chemical # and Name 086002 Warfarin	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3282-3 3282-4 3282-15 3282-32					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

DATA CALL-IN RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
003282 D-CON COMPANY INC 225 SUMMIT AVENUE MONTVALE NJ, 07645	0011 Warfarin & its Na salt Chemical # and Name 086003 Sodium warfarin	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3282-9					

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

Generic Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

INSTRUCTIONS

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

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

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

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP __%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date of your receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. 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 and that I will provide the protocols and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that

has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address 003282
D-CON COMPANY INC
225 SUMMIT AVENUE
MONTVALE NJ 07645

2. Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name 086002
Warfarin

3. Date and Type of DCI
GENERIC
5/21/91

4. Guideline Requirement Number		5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					ALL	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mfg. proc					ALL	TGAI	12 mos.	
61-2(b)	*	Discussion of Impurities					ALL	TGAI	12 mos.	
62-1	*	Preliminary Analysis					ALL	TGAI	12 mos.	
62-2	*	Certification of limits					ALL	TGAI	12 mos.	
62-3	*	Analytical Method					ALL	TGAI	12 mos.	
63-2		Color					ALL	TGAI	12 mos.	
63-3	*	Physical State					ALL	TGAI	12 mos.	
63-4	*	Odor					ALL	TGAI	12 mos.	
63-7	*	Density					ALL	TGAI	12 mos.	
63-8	*	Solubility					ALL	TGAI	12 mos.	
63-9	*	Vapor Pressure					ALL	TGAI	12 mos.	
63-12	*	pH					ALL	TGAI	12 mos.	
63-13	*	Stability					ALL	TGAI	12 mos.	
171-4(i)	*	Mag. of res. food handling		Y			L	*	24 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086002 Warfarin

GUIDELINE	COMMENT
61-1	FOOTNOTE A - For EPA Registration Nos. 2749-31, 6720-312, 900-130, and 10813-1, the following information must be provided: 1) a general characterization of the process (e.g., batch or continous); 2) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; 3) a description of the equipment used; 4) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; 5) a description of the procedures used to assure consistent composition of the substance produced (quality control methods); 6) the name and address of the producer if different from the registrant; 7) the brand name, trade name, or other commercial designation, and information concerning the composition of each starting material; 8) a flow chart of the chemical equations of each intended reaction occuring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; 9) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced). In addition, the following information must be provided for the specific products listed in brackets: a general characterization of the process (e.g., batch or continous) [10442-5 and 12455-26]; the relative amounts of the materials used to produce the product [3282-32 and 12455-26]; the order in which the materials used to produce the product are added [12455-26]; a description of the equipment used [3282-32 and 12455-26]; quality control methods [12455-26]; the name and address of the producer and information concerning the composition of each starting material [3282-32 and 12455-26]; the duration of each step of the process [10442-5, 3282-32, and 12455-26]; reaction conditions [12455-26]; and purification procedures [12455-26]. These data will satisfy this requirement for all repackaged products.
61-2(a)	See Footnote A.
61-2(b)	For each technical grade of the active ingredient (TGAI) except EPA Registration No.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086002 Warfarin

GUIDELINE	COMMENT
	12455-26, a discussion regarding the orgin of the following impurities must be provided: 1) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and 2) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For repackaged products, the discussion of potential impurities may be confined to potential postproduction contamination from packaging materials.
62-1	FOOTNOTE B - For each TGAI, except EPA Registration No. 12455-26, the registrant must provide preliminary analyses of five or more representative samples to quantify the active ingredient and identify all impurities present at 0.1%. If the product is produced by a batch process, each sample should be taken from a different batch of the product. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the indentity and quantity of each ingredient for which analysis is conducted along, with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the TGAI must be provided. These data will satisfy this requirement for all repackaged products.
62-2	See Footnote B under Preliminary Analysis, 62-1.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086002 Warfarin

GUIDELINE	COMMENT
62-3	See Footnote B.
63-3	Data are required for product 12455-26.
63-4	Data are required for products 2749-31 and 10813-1.
63-7	Data are required for products 2749-31, 6900-130, 10813-1, and 12455-26.
63-8	Data are required for solubility inpolar and nonpolar solvents for all technical grade products except 10442-5.
63-9	Data are required for all technical grade products.
63-12	Data are required for all technial grade products except 10442-5.
63-13	Data are required for all technical grade products.
171-4(i)	TEST SUBSTANCE: PAIRA, TEP, AND METABOLITES. The registrant may either amend the current label for the 1% dust tracking powder to include the language as required in the RED which accompanied this document or supply residue data to support the tracking powder use. The residue data that would be required are: a) Data depicting the nature of the residue in representative food products from typical food/feed handling establishments resulting from known contamination by [14c] warfarin (labeled in all three rings). Characterization of residues must be conducted in samples representing the range of normal shelf life for the food/feed products; and b) Data depicting the magnitude of residues of concern in food/feed products resulting from normal application

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086002 Warfarin

GUIDELINE	COMMENT
	of the 1% D formualtion as a tracking powder, at the 1x and exaggerated rates, to food/feed handling premises (two representative types of each food handling establishment as listed in Table 1 of Subdivison O of the Pesticide Assessment Guidelines). Test conducted must be representative examples of worst case scenarios for potential residue contamination of food/feed products which might include, but are not limited to, some of the following: i) tracking of residues from treated areas by rodents or insects; ii) contact of packaged or open foods/feeds with treated surfaces; iii) distribution of particular matter through forced ventilation systems; and iv) routine floor cleaning and cleaning specifically designed to remove old excess tracking powder. Exposure situations in grocery stores and restaurants must include a representative range of foods such as oily foods, baked cereal products, raw and cooked meats, and fresh fruits and vegetables. [The registrant is urged to complete and submit the required food/feed degradation study using radiolabeled material prior to initiation of these residue trials.]

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address 003282
D-CON COMPANY INC
225 SUMMIT AVENUE
MONTVALE NJ 07645

2. Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name 086003
Sodium warfarin

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number		5. Study Title	CONTROL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					ALL	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mnfg. proc					ALL	TGAI	12 mos.	
61-2(b)	*	Discussion of Impurities					ALL	TGAI	12 mos.	
62-1	*	Preliminary Analysis					ALL	TGAI	12 mos.	
62-2	*	Certification of limits					ALL	TGAI	12 mos.	
62-3	*	Analytical Method					ALL	TGAI	12 mos.	
63-2		Color					ALL	TGAI	12 mos.	
63-3	*	Physical State					ALL	TGAI	12 mos.	
63-4	*	Odor					ALL	TGAI	12 mos.	
63-7	*	Density					ALL	TGAI	12 mos.	
63-8	*	Solubility					ALL	TGAI	12 mos.	
63-9	*	Vapor Pressure					ALL	TGAI	12 mos.	
63-12	*	pH					ALL	TGAI	12 mos.	
63-13	*	Stability					ALL	TGAI	12 mos.	
72-1(a)	*	Fish toxicity bluegill					CK	TGAI	12 mos.	
72-1(c)	*	Fish toxicity rainbow trout					CKLMO	TGAI	12 mos.	
72-2(a)	*	Invertebrate toxicity					CKLMO	TGAI	12 mos.	

10. Certification

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
003282 D-CON COMPANY INC 225 SUMMIT AVENUE MONTVALE NJ 07645	0011 Warfarin & its Na salt Chemical # and Name 086003 Sodium warfarin	GENERIC

4. Guideline Requirement Number	5. Study Title	PDCI	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
171-4(i) *	Mag. of res. food handling		Y			L	*	24 mos.	

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

Date

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086003 Sodium warfarin

GUIDELINE	COMMENT
61-1	FOOTNOTE A - For EPA Registration Nos. 2749-31, 6720-312, 6900-130, and 10813-1, the following information must be provided: 1) a general characterization of the process (e.g., batch or continuous); 2) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; 3) a description of the equipment used; 4) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and 5) a description of the procedures used to assure consistent composition of the substance produced (quality control methods); 6) the name and address of the producer if different from the registrant; 7) the brand name, trade name, or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; 8) a flow chart of the chemical equations of each intended reaction occuring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; and 9) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced). In addition, the following information must be provided for the specific products listed in brackets: a general characterization of the process (e.g. batch or continous) [10442-5 and 12455-26]; the relative amounts of the materials used to produce the product [3282-32 and 12455-26]; the order in which the materials used to produce the product are added [12455-26]; a description of the equipment used [3282-32 and 12455-26]; quality control methods [12455-26]; the name and address of the producer and information concerning the composition of each starting material [3282-32 and 12455-26]; the duration of each step of the process [10442-5, 3282-32, 12455-26]; reaction conditions [12455-26]; and purification procedures [12455-26]. These data will satisfy this requirement for all repackaged products.
61-2(a)	See Footnote A.
61-2(b)	For each technical grade of the active ingredient (TGAI), except EPA Registration No.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086003 Sodium warfarin

GUIDELINE	COMMENT
	12455-26, a discussion regarding the orgin of the following potential impurities must be provided: i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and 2) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For repackaged products, the discussion of potential impurities may be confined to potential postproduction contamination from packaging materials.
62-1	FOOTNOTE B - For each TGAI, except EPA Registration No. 12455-26 the registrant must provide preliminary analyses of five or more representative samples to quantify the active ingredient and identify all impurities present at 0.1%. If the product is produced by a batch process, each sample should be taken from a different batch of the product. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantify of each ingredient for which analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the TGAI must be provided. These data will satisfy this requirement for all repackaged products.
62-2	See Footnote B.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086003 Sodium warfarin

GUIDELINE	COMMENT
62-3	See Footnote B.
63-3	Data are required for product 12455-26.
63-4	Data are required for products 2749-31 and 10813-1.
63-7	Data are required for products 2749-31, 6900-130, 10813-1 and 12455-26.
63-8	Data are required for solubility in polar and nonpolar solvents for all technical grade products except 10422-5.
63-9	Data are required for all technical grade products.
63-12	Data are required for all technical grade products except 10442-5.
63-13	Data are required for all technical grade products.
72-1(a)	Testing is required for the sodium salt of warfarin.
72-1(c)	Testing is required for the sodium salt of warfarin.
72-2(a)	Testing is required for the sodium salt of warfarin.
171-4(i)	TEST SUBSTANCE: PAIRA, TEP, AND METABOLITES The registrant may either amend the current label for the 1% dust tracking powder to include the language as required in the accompanying RED or supply residue data to support the tracking powder use. The residue

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0011 Warfarin & its Na salt
Chemical # and Name
086003 Sodium warfarin

GUIDELINE	COMMENT
	data that would be required are: a) Data depicting the nature of the residue in representative food products from typical food/feed handling establishments resulting from known contamination by [14C] warfarin (labeled in all three rings.) Characterization of residues must be conducted in samples representing the range of normal shelf life for the food/feed products; and b) Data depicting the magnitude of residues concern in food/feed products resulting from normal application of the 1%D formulation as a tracking powder, at the 1x and exaggerated rates, to food/feed handling premises (two representative types of each food handling establishment as listed in Table 1 of Subdivision O of the Pesticide Assessment Guidelines). Tests conducted must be representative examples of worst case scenarios for potential residue contamination of food/feed products which might include, but are not limited to, some of the following: i)tracking of residues from treated areas by rodents or insects; ii) contact of packaged or open foods/feeds with treated surfaces; iii)distribution of particular matter through forced ventialation systems; and iv) routine floor cleaning and cleaning specifically designed to remove old or excess tracking powder. Exposure situations in grocery stores and restaurants must include a representative range of foods such as oily foods, baked cereal products, raw and cooked meats, and fresh fruits and vegetables. [The registrant is urged to complete and submit the required food/feed degradation study using radiolabeled material prior to initiation of these residue trials.]

ATTACHMENT C

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORM
AND
PRODUCT SPECIFIC REQUIREMENT STATUS AND
REGISTRANT'S RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

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

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

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)** and complete and submit the **"Generic Data Exemption" form**; 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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA

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

DATA CALL-IN RESPONSE

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

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

SAMPLE - DO NOT USE

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
NOTT MANUFACTURING COMPANY INC. BO 685 PLEASANT VALLEY NY. 12	0011 Warfarin Chemical # and Name 086002 Warfarin	PRODUCT SPECIFIC

4. EPA Product Registration Number	5. I wish to cancel this product registration voluntary	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA Registration numbers listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrants' Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrants' Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrants' Response."
58		N.A.	N.A.		

8. Certification
I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative

9. Date

10. Name of Company Contact

11. Phone Number

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

Product Specific Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of product specific data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

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 <u>only one</u> of the following response codes <u>for each data requirement</u> 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 and a completed "Certification With Respect To Data Compensation Requirements" form. I understand that this option is available only for acute toxicity or certain efficacy

data and only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing

another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed **"Certification With Respect To Data Compensation Requirements" form.**

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

Items 10-13. Self-explanatory.

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

another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

Items 10-13. Self-explanatory.

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

DRAFT

EPA

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

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

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

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

1. Company name and Address
NOTT MANUFACTURING COMPANY INC.
BOX 685
PLEASANT VALLEY, NY. 12569

2. Case # and Name 0011 Warfarin
Chemical # and Name
086002 Warfarin
EPA Reg. No. 358-128

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 358-RD-350

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	Progress Reports 2 yrs	Progress Reports 3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Product identity					ALL	EP	8 mos.	
61-2(a)	Begin. mat. & mfg. proc.					ALL	EP	8 mos.	
61-2(b)	Discussion of impurities					ALL	EP	8 mos.	
62-1	Preliminary analysis					ALL	EP	8 mos.	
62-2	Certification of limits					ALL	EP	8 mos.	
62-3	Analytical method					ALL	EP	8 mos.	
63-2	Color					ALL	EP	8 mos.	
63-3	Physical state					ALL	EP	8 mos.	
63-4	Odor					ALL	EP	8 mos.	
63-5	Melting point					ALL	EP	8 mos.	
63-6	Boiling point					ALL	EP	8 mos.	
63-7	Density, bulk density or sp. gr.					ALL	EP	8 mos.	
63-8	Solubility					ALL	EP	8 mos.	
63-9	Vapor pressure					ALL	EP	8 mos.	
63-10	Dissociation constant					ALL	EP	8 mos.	
63-11	Oct/Water partition coef.					ALL	EP	8 mos.	
63-12	pH					ALL	EP	8 mos.	
63-13	Stability					ALL	EP	8 mos.	

10. Certification
I certify that the statements that I have made on this form and all attachments thereto 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 and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

EPA

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

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
NOTT MANUFACTURING COMPANY INC. BOX 685 PLEASANT VALLEY, NY. 12569	0011 Warfarin Chemical # and Name 086002 Warfarin EPA Reg. No. 358-128	PRODUCT SPECIFIC ID# 358-RD-350

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	Progress Reports 2 yrs	Progress Reports 3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-14	Oxidizing/Reducing Action					ALL	EP	8 mos.	
63-15	Flammability					ALL	EP	8 mos.	
63-16	Explodability					ALL	EP	8 mos.	
63-17	Storage stability					ALL	EP	8 mos.	
63-18	Viscosity					ALL	EP	8 mos.	
63-19	Miscibility					ALL	EP	8 mos.	
63-20	Corrosion characteristics					ALL	EP	8 mos.	
63-21	Dielectric breakdown voltage					ALL	EP	8 mos.	
81-1	Acute oral tox. rat					ALL	EP	8 mos.	
81-2	Acute dermal tox. rabt./rat/g.pig					ALL	EP	8 mos.	
81-3	Acute inhal. tox rat					ALL	EP	8 mos.	
81-4	Primary eye irritation-rabbit					ALL	EP	8 mos.	
81-5	Primary dermal irritation					ALL	EP	8 mos.	
81-6	Dermal sensitization					ALL	EP	8 mos.	
96-10(c)	Product performance Laboratory efficacy studies Norway rat, house mouse					ALL	EP	8 mos.	

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

Date

INSTRUCTIONS FOR COMPLETING EFFICACY DATA REQUIREMENTS FORM

For product performance data requirements, 96-10C, registrants must use the Efficacy Data Requirements Status and Registrants Response Form, that is attached directly to the Registrants Status and Requirements Response Form. In responding, you must circle the test number of every study that is appropriate to your product. In the Column next to "TEST NUMBER", you must indicate how you will statisfy the requirement. The options available are the same as those available for all product specific data requirements.

EFFICACY DATA

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

FOR END-USE PRODUCTS OF WARFARIN AND ITS SODIUM SALT

Test No.[a/]	Response Column[b/]	Test Name[c/]	Type of Claim
1.201		Standard Norway Rat Anticoagulant Liquid Bait Laboratory Test Method	Liquid baits for control of Norway rats and/or roof rats.
1.202		Standard House Mouse Anticoagulant Liquid Bait Laboratory Test Method	Liquid baits for control of house mice.
1.203		Standard Norway Rat Anticoagulant Dry Bait Test Method	Ready-to-use dry baits (lacking "waterproof" claims) for control of Norway and/or roof rats.
1.204		Standard House Mouse Anticoagulant Dry Bait Test Method	Ready-to-use dry baits (lacking "waterproof" claims) for control of house mice.

CERTIFICATION

I certify that the statements that I have made on this form and all attachments thereto 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. I also certify that I have reviewed all of the label claims for my proudct and indicated how I will satisfy all efficacy data requirements.

_____ _____

SIGNATURE AND TITLE OF COMPANY'S AUTHORIZED REPRESENTATIVE DATE

_____ _____

COMPANY CONTACT PHONE NUMBER

EFFICACY DATA

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

FOR END-USE PRODUCTS OF WARFARIN AND ITS SODIUM SALT

Test No.[a/]	Response Column[b/]	Test Name[c/]	Type of Claim
1.205		Standard Norway Rat Anticoagulant Tracking Powder Efficacy Laboratory Test Method	Tracking powders for control of Norway and/or roof rats.
1.212		Standard House Mouse Anticoagulant Tracking Powder Efficacy Laboratory Test Method	Tracking powders for control of house mice.
1.213		Standard Norway Rat Anticoagulant Wax Block Wax Pellet Laboratory Test Method	All Norway and/or roof rat ready-to-use and baits claimed to be "waterproof", "suitable for use in wet or damp areas", "mold-resistant", "weatherproof", "suitable for use in sewers", "weatherproof", "weather-protected", etc.

CERTIFICATION

I certify that the statements that I have made on this form and all attachments thereto 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. I also certify that I have reviewed all of the label claims for my proudct and indicated how I will satisfy all efficacy data requirements.

_____ _____

SIGNATURE AND TITLE OF COMPANY'S AUTHORIZED REPRESENTATIVE DATE

_____ _____

COMPANY CONTACT PHONE NUMBER

EFFICACY DATA

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

FOR END-USE PRODUCTS OF WARFARIN AND ITS SODIUM SALT

Test No.[a/]	Response Column[b/]	Test Name[c/]	Type of Claim
1.214		Standard House Mouse Anticoagulant Wax Block and Wax Pellet Laboratory Test Method	All house mouse ready-to-use baits claimed to be"waterproof", "suitable for use in wet or damp areas", "mold-resistant", "weather-proof", "suitable for use in sewers", "weather-proof", "weather-protected", etc.
1.217		Standard Rat Anticoagulant Place-Pack Dry Bait Laboratory Test Method	For all ready-to-use Norway and/or roof rat baits sold in place-packs, this test is required in addition to 1.203.
1.218		Standard House Mouse Anticoagulant Place-Pack Dry Bait Laboratory Test Method	For all ready-to-use house mouse baits sold in place-packs, this test is required in addition to 1.204.

CERTIFICATION

I certify that the statements that I have made on this form and all attachments thereto 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. I also certify that I have reviewed all of the label claims for my proudct and indicated how I will satisfy all efficacy data requirements.

_____ _____

SIGNATURE AND TITLE OF COMPANY'S AUTHORIZED REPRESENTATIVE DATE

_____ _____

COMPANY CONTACT PHONE NUMBER

EFF. .Y DATA

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

FOR END-USE PRODUCTS OF WARFARIN AND ITS SODIUM SALT

Test No.[a/]	Response Column[b/]	Test Name[c/]	Type of Claim
1.221		Proposed Norway Rat Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method	All solid concentrates with end-use directions for control of Norway and/or roof rats.
1.225		Proposed House Mouse Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method	All solid concentrates with end-use directions with claims for control of house mice.

CERTIFICATION

I certify that the statements that I have made on this form and all attachments thereto 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. I also certify that I have reviewed all of the label claims for my proudct and indicated how I will satisfy all efficacy data requirements.

_____ _____

SIGNATURE AND TITLE OF COMPANY'S AUTHORIZED REPRESENTATIVE DATE

_____ _____

COMPANY CONTACT PHONE NUMBER

EF. .CY DATA

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

FOR END-USE PRODUCTS OF WARFARIN AND ITS SODIUM SALT

a/ Circle the test number of each efficacy study which applies to your product based on all labeling claims.

b/ For each test number circled, indicate in the Response Column how you will fulfill the requirement. The options available are: (1) I will generate and submit data within the specified timeframe (developing data); (2) I have entered into an agreement with one or more registrants to develop data jointly (agreement to cost sharing); (3) I have made 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); and (7) I am requesting a data waiver.

c/ Registrant has 9 months to submit all laboratory test data and 18 months to submit all field test data. Only laboratory testing is required for commensal rodents (i.e., house mice and Norway rats).

CERTIFICATION

I certify that the statements that I have made on this form and all attachments thereto 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. I also certify that I have reviewed all of the label claims for my proudct and indicated how I will satisfy all efficacy data requirements.

_____ _____

SIGNATURE AND TITLE OF COMPANY'S AUTHORIZED REPRESENTATIVE DATE

_____ _____

COMPANY CONTACT PHONE NUMBER

ATTACHMENT D

FORMATTED/SAMPLE LABELS

[FORMAT LABEL - READY-TO-USE WARFARIN DRY BAIT]

[Front Panel]

[PRODUCT NAME]

Kills Norway Rats, Roof Rats, and House Mice

ACTIVE INGREDIENT:

Warfarin [3-(alpha-Acetonylbenzyl)-4-hydroxycoumarin]	_____%
INERT INGREDIENTS	_____%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN [12 pt[1]]

CAUTION [18 pt[1]]

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

[Company Name and Address]

EPA Reg. No. _____

EPA Est. No. _____

NET CONTENTS _____

---

[1] Assumes a front panel of over 30 sq. in.

[FORMAT LABEL - READY-TO-USE WARFARIN DRY BAIT]

[Left Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS - For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS - Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS

RATS: Apply 4 to 16 oz. of bait per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days.

MICE: Apply 1/4 to 1/2 oz. (1-2 level tablespoons) of bait at 8- to 12-foot intervals. Larger placements (up to 2 oz.) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days.

[FORMAT LABEL - READY-TO-USE WARFARIN DRY BAIT]

[Right Panel]

APPLICATION DIRECTIONS (Continued from left panel)

RATS/ MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead animals and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

[For Household Products]

STORAGE AND DISPOSAL [12 pt[1]]
Storage: Store only in original container, in a dry place inaccessible to children and pets.
Disposal: Do not reuse empty container.[2] Securely wrap in newspaper and discard in trash.

[For Non-Household Products]

STORAGE AND DISPOSAL [12 pt[1]]
Do not contaminate water, food or feed by storage or disposal.
STORAGE: [Develop statements based on "Storage Instructions" factors 1-5 in PR Notice 83-3, pp 2-3.]
PESTICIDE DISPOSAL: [Use paragraph 4 on p. 4 of PR Notice 83-3.
CONTAINER DISPOSAL: [See Appendix A on p. 7 of PR Notice 83-3.]

PRECAUTIONARY STATEMENTS:
HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding.

NOTE TO PHYSICIAN - If ingested, administer Vitamin K_1 intramuscularly or orally, as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply this product to water, swamps, bogs, or potholes.

---

[1] Assumes a panel of over 30 sq. in.
[2] If container is a bottle, can, or jar, add "Rinse container thoroughly." here.

[FORMAT LABEL - WARFARIN CONCENTRATE WITH MIXING AND USE DIRECTIONS FOR DRY BAITS]

[Front Panel]

[PRODUCT NAME]

A Concentrate for Preparing Baits to Kill
Norway Rats, Roof Rats, and House Mice

ACTIVE INGREDIENT:	
Warfarin [3-(alpha-Acetonylbenzyl)-4-hydroxycoumarin]	_____%
INERT INGREDIENTS	_____%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN [12 pt[1]]

CAUTION [18 pt[1]]

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

[Company Name and Address]

EPA Reg. No. _____

EPA Est. No. _____

NET CONTENTS _____

---

[1] Assumes a front panel of over 30 sq. in.

[FORMAT LABEL - WARFARIN CONCENTRATE FOR MIXING, USING DRY BAITS, Left Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS - For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS - Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

MIXING DIRECTIONS

Thoroughly mix one part of concentrate with [specify number] parts of suitable bait materials (cereal grains, fish, meats, vegetables, etc.) plus binding agents and sweeteners, if needed. For example, mix one part of concentrate with [provide recipe for mixing a bait formulation has performed adequately in laboratory efficacy tests with rats and mice.].

Bait materials resembling human foods must be altered in form by crushing, balling, or pelletizing so that they are not readily recognizable as foods.

APPLICATION DIRECTIONS

RATS: Apply 4 to 16 oz. of bait per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days.

MICE: Apply 1/4 to 1/2 oz. (1-2 level tablespoons) of bait at 8- to 12-foot intervals. Larger placements (up to 2 oz.) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days.

[FORMAT LABEL - WARFARIN CONCENTRATE FOR MIXING, USING DRY BAITS, Right Panel]

APPLICATION DIRECTIONS (Continued from left panel)

RATS/ MICE: Replace contaminated or spoiled bait immediately. Check perishable baits daily. Collect and dispose of all dead animals and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

[For Household Products]

STORAGE AND DISPOSAL [12 pt[1]]

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container.[2] Securely wrap in newspaper and discard in trash.

[For Non-Household Products]

STORAGE AND DISPOSAL [12 pt[1]]

Do not contaminate water, food or feed by storage or disposal.

STORAGE: [Develop statements based on "Storage Instructions" factors 1-5 in PR Notice 83-3, pp 2-3.]

PESTICIDE DISPOSAL: [Use paragraph 2 or 4 on p. 4, of PR Notice 83-3.
Use ¶ 2 if product contains >0.3% active ingredient.
Use ¶ 4 if product contains ≤0.3% active ingredient.]

CONTAINER DISPOSAL: [See Appendix A on p. 7 of PR Notice 83.3.]

PRECAUTIONARY STATEMENTS:
HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. Exposure during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. When mixing baits, wear dust respirator[3] and rubber gloves. If product contacts skin, wash with soap or water.

NOTE TO PHYSICIAN - If ingested, administer Vitamin K_1 intramuscularly or orally, as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply this product to water, swamps, bogs, or potholes.

---

[1] Assumes a panel of over 30 sq. in..
[2] If container is a bottle, can, or jar, add "Rinse container thoroughly." here.
[3] Use the words "dust respirator and" if the product is a respirable dust.

[FORMAT LABEL - SODIUM SALT OF WARFARIN CONCENTRATE WITH MIXING AND END-USE DIRECTIONS FOR LIQUID BAITS]

[Front Panel]

[PRODUCT NAME]

A Concentrate for Preparing Liquid Baits to Kill Norway Rats, Roof Rats, and House Mice

ACTIVE INGREDIENT:	
Sodium Salt of Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin, sodium salt]	_____%
INERT INGREDIENTS	_____%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN [12 pt[1]]

CAUTION [18 pt[1]]

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

[Company Name and Address]

EPA Reg. No. _____

EPA Est. No. _____

NET CONTENTS _____

---

[1] Assumes a front panel of over 30 sq. in.

[FORMAT LABEL - SODIUM SALT OF WARFARIN CONCENTRATES, Left Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS - For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures. Do not apply bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS - Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain or snow. Limit alternative sources of water as much as possible.

MIXING DIRECTIONS

Mix ___ oz. of concentrate per quart of water. [If sweetener was used for efficacy tests, indicate the sweetener to use and how much to add per quart.]

APPLICATION DIRECTIONS

RATS: Use a minimum of 1 pint of liquid bait per placement. Apply liquid bait in dispensers such as chick founts or covered bait stations adapted for containing and dispensing liquid baits. Maintain an uninterrupted supply of fresh bait for at least 10 days.

MICE: Use 4-8 fluid ounces of liquid bait per placement. Apply liquid bait in dispensers such as chick founts or covered bait stations adapted for containing and dispensing liquid baits. Maintain an uninterrupted supply of fresh bait for at least 15 days.

[FORMAT LABEL - SODIUM SALT OF WARFARIN CONCENTRATES, Right Panel]

APPLICATION DIRECTIONS (Continued from left panel)

RATS/ MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead animals and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

[For Household Products]

STORAGE AND DISPOSAL [12 pt[1]]

Storage: Store only in original container, in a dry place inaccessible to children and pets

Disposal: Do not reuse empty container.[2] Securely wrap in newspaper and discard in trash.

[For Non-Household Products]

STORAGE AND DISPOSAL [12 pt[1]]

Do not contaminate water, food or feed by storage or disposal.

STORAGE: [Develop statements based on "Storage Instructions" factors 1-5 in PR Notice 83-3, pp 2-3.]

PESTICIDE DISPOSAL: [Use paragraph 2 or 4 on p. 4 of PR Notice 83-3.
Use ¶ 2 if product contains >0.3% active ingredient.
Use ¶ 4 if product contains ≤0.3% active ingredient.]

CONTAINER DISPOSAL: [See Appendix A on p. 7 of PR Notice 83.3.]

PRECAUTIONARY STATEMENTS:
HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding.

NOTE TO PHYSICIAN - If ingested, administer Vitamin K_1 intramuscularly or orally, as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply bait made from this product to water, swamps, bogs, and ponds.

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[1] Assumes a panel of over 30 sq. in.
[2] If container is a bottle, can, or jar, add "Rinse container thoroughly." here.

[FORMAT LABEL - WARFARIN TRACKING POWDER]

[Front Panel]

RESTRICTED USE PESTICIDE

Due to Need for Specialized Training
to Ensure Proper Use.

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

[PRODUCT NAME]

Kills Norway Rats, Roof Rats, and House Mice

FOR INDOOR USE ONLY

ACTIVE INGREDIENT:

Warfarin [3-(alpha-Acetonylbenzyl)-4-hydroxycoumarin]	_____%
INERT INGREDIENTS	_____%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE PANELS FOR
ADDITIONAL PRECAUTIONARY STATEMENTS

[Company Name and Address]

EPA Reg. No. _____

EPA Est. No. _____

NET CONTENTS _____

[FORMAT LABEL - WARFARIN TRACKING POWDER]

[Left Panel]

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed. Do not inhale powder. Wear dust respirator. This product can be absorbed through the skin so it should be handled with gloves. Keep away from humans, domestic animals, or pets. This material may reduce the clotting ability of the blood and cause bleeding. Exposure to warfarin during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects.

NOTE TO PHYSICIAN - If ingested, administer Vitamin K_1 intramuscularly or orally, as indicated in bishydroxycourmarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply this product to water, swaps, bogs, or potholes.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal

STORAGE: [Develop statements based on "Storage Instructions" factors 1-5 in PR Notice 83-3, pp 2-3.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal or discharge or excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: [See Appendix A on p. 7 of PR Notice 83-3.]

[FORMAT LABEL - WARFARIN TRACKING POWDER]

[Right Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: Use to control Norway rats, roof rats, and house mice inside homes, industrial and agricultural buildings, and similar man-made structures. Tracking powder may also be dusted into rat burrows that are located along the periphery of buildings and that are likely to serve as routes of entry into these structures.

Tracking powder must be placed in locations not accessible to children, pets, domestic animals, or nontarget wildlife. If using this product in agricultural buildings where livestock feeds are stored, or in commercial food service, food manufacturing or food processing establishments, limit treatments to concealed, inaccessible places such as spaces between floors and walls. Do not apply tracking powder along walls, in corners, in open floor areas, or on rafters of rooms in which food or feed is handled or stored.

SELECTION OF TREATMENT AREAS: Determine dry areas where rats and mice will most likely pick up the powder on their feet or fur and ingest it during grooming. Generally, these areas are in spaces between floors and walls, by gnawed openings and burrows, in concealed places, along walls and in corners (where permitted), or in other appropriate locations where signs of rodents have been observed. Remove goods piled directly on the floor and place on skids. Use boxes or other obstacles to force rodents to travel through constricted areas. Give special attention to the climbing ability of roof rats. For this species (where permitted), use cardboard tubes or wooden tunnels securely attached to rafters or other horizontal surfaces where rats will pass. Employ tubes long enough to minimize spillage of powder through the ends.

APPLICATION DIRECTIONS: For house mice, use at the rate of 1 oz. powder per 2.5 sq. ft. of runway area. For Norway and roof rats, use at the rate of 2 oz. powder per 2.5 sq. ft. of runway area. Apply the powder into rodent burrow holes or within walls with a hand bulb or similar duster. Do not use power dusting devices. Sprinkle the powder in patches in such a manner as to expose the rodent to it. Patch size may be (but need not be limited to) 6" X 12" and should be adapted to each situation. For burrows that are located along the periphery of buildings and that are likely to serve as routes of entry into these structures, place about 5 grams of tracking powder in each burrow with a foot-pump duster (about 15 pumps). Close burrows with soil, loose leaves, or paper. Retreat if burrows are re-opened.

Maintain powder in treated areas for at least 20 days. Collect and dispose of all dead animals. Dispose of used powder when control program is finished.

Remove as many sources of food, water, and harborage as possible. Repeat treatment if reinfestation occurs.

ATTACHMENT E

EPA GROUPING OF END-USE PRODUCTS FOR MEETING ACUTE TOXICOLOGY DATA REQUIREMENTS FOR REREGISTRATION

EPA'S BATCHING OF WARFARIN END-USE 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 end-use products containing the active ingredient warfarin, 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, and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to 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.

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.

The following table shows 4 batches including 85 products containing the active ingredient warfarin. Note that another 3 products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of the products not listed are responsible for meeting the acute toxicity data requirements for each product.

Table

Batch No.	EPA Reg. No.	% Warfarin	Formulation Type
1.	655-318	99.85	Technical
	2393-447	100.	Technical
	3282-32	98.	Technical
	6720-171	100.	Technical
	10442-5	100.	Technical
	12455-26	99.9	Technical
2.	655-19	0.5	Manufacturing-use
	655-246	0.5	Manufacturing-use
	655-443	1.0	Powder
	655-503	0.5	Manufacturing-use
	2393-19	0.5	* Concentrate
	2393-149	0.5	* Concentrate
	2393-387	0.5	Manufacturing-use
	2393-483	0.5	* Concentrate
	3282-3	0.3	* Concentrate
	5887-42	0.5	Manufacturing-use
	6720-53	0.5	* Concentrate
	6720-291	0.5	* Concentrate
	7276-8	0.54	* Concentrate
	10370-119	0.5	* Concentrate
	12455-22	0.54	* Liquid concentrate
	12455-27	0.5	Manufacturing-use
	12455-28	0.5	* Concentrate

* These products are concentrates used for making baits.

Table (Continued)

Batch No.	EPA Reg. No.	% Warfarin	Formulation Type
3.	407-435	0.025	Bait
	655-502	0.025	Bait
	655-504	0.5	*Concentrate
	3282-4	0.25	Bait
	3487-19	0.025	Bait
	7122-35	0.025	Bait
	8580-1	0.025	Bait
	12455-15	0.025	Bait
4.	584-5	0.025	Bait
	602-255	0.025	Bait
	602-266	0.025	Bait
	655-515	0.025	Bait
	655-539	0.025	Bait
	690-28	0.025	Bait
	690-32	0.025	Bait
	746-124	0.025	Bait
	995-41	0.025	Bait
	1304-19	0.025	Bait
	2006-43	0.025	Bait
	2006-48	0.025	Bait
	2393-145	0.025	Bait
	2393-166	0.025	Bait
	2393-363	0.025	Bait
	2393-388	0.025	Bait
	2393-452	0.025	Bait
	2724-154	0.025	Bait
	2724-444	0.025	Bait
	2724-445	0.025	Bait
	3282-4	0.025	Bait
	3282-9	0.054	Bait
	3282-15	0.025	Bait
	3536-4	0.025	Bait
	3941-21	0.025	Bait
	3941-26	0.025	Bait
	4271-7	0.025	Bait
	5836-3	0.025	Bait
	5887-30	0.025	Bait
	5887-51	0.025	Bait
	5887-98	0.025	Bait
	6383-1	0.025	Bait
	6653-1	0.025	Bait
	6720-44	0.025	Bait
	6720-319	0.025	Bait
	6720-333	0.025	Bait
	6720-345	0.025	Bait
	7276-1	0.025	Bait
	7276-11	0.025	Bait

* This is a concentrate with directions for mixing, and applying baits.

Table (Continued)

Batch No.	EPA Reg. No.	% Warfarin	Formulation Type
	7276-14	0.025	Bait
	7276-16	0.025	Bait
	7276-17	0.025	Bait
	7455-12	0.025	Bait
	7537-2	0.025	Bait
	8845-39	0.025	Bait
	8848-2	0.025	Bait
	9561-3	0.025	Bait
	9691-1	0.025	Bait
	10370-120	0.025	Bait
	17975-1	0.025	Bait
	34274-2	0.025	Bait
	45722-1	0.025	Bait
	47000-38	0.025	Bait
	56176-1	0.025	Bait

ATTACHMENT F

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Name of technical material tested (include product name and trade name, if appropriate)
2. ___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3. ___ Name and upper certified limit for each impurity or each group of impurities present at ≥ 0.1% by weight and certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%
4. ___ Purpose of each active ingredient and each intentionally-added inert
5. ___ Chemical name from Chemical Abstracts Index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6. ___ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
7. ___ Description of each beginning material in the manufacturing process
   - ___ EPA Registration Number if registered; for other beginning materials, the following:
   - ___ Name and address of manufacturer or supplier
   - ___ Brand name, trade name or commercial designation
   - ___ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity
8. ___ Description of manufacturing process
   - ___ Statement of whether batch or continuous process
   - ___ Relative amounts of beginning materials and order in which they are added
   - ___ Description of equipment
   - ___ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained
   - ___ Statement of whether process involves intended chemical reactions
   - ___ Flow chart with chemical equations for each intended chemical reaction
   - ___ Duration of each step of process
   - ___ Description of purification procedures
   - ___ Description of measures taken to assure quality of final product
9. ___ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at ≥ 0.1% or was found at ≥ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3)

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

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 1, 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement of Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration, and certified limits.
3. Name and upper limit for all impurities present at $\geq$ 0.1% and those toxicologically significant impurities present at <0.1%.
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental or internal code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at ≥ 0.1%
2. ___ Degree of accountability or closure ≥ ca 98%
3. ___ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans) [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]
4. ___ Complete and detailed description of each step in analytical method used to analyze above samples
5. ___ Statement of precision and accuracy of analytical method used to analyze above samples
6. ___ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient
7. ___ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined
8. ___ Upper certified limit proposed for each impurity present at ≥ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined
9. ___ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described
10. ___ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy

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

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

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

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

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

63-3 Physical State

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

63-4 Odor

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

63-5 Melting Point

___ Reported in °C
___ Any observed decomposition reported

63-6 Boiling Point

___ Reported in °C
___ Pressure under which B.P. measured reported
___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

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

63-8 Solubility

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

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

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

*63-12 pH

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

63-13 Stability

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

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

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

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

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

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

SUBDIVISION F

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing.
7. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
8. See items 6 and 7
9. Summarization of body weights
10. Summarization of gross necropsy
11. Significance of changes from the Acceptance Criteria

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\leq$ 2 or $\geq$ 11.5.
3.*____ 6 adult rabbits
4. ____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.*____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6. ____ Solid or granular test material ground to a fine dust.
7. ____ Eyes not washed for at least 24 hours.
8. ____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*____ Individual observations for the entire day of dosing.
10.*____ Individual daily observations.

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

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State of material is corrosive, cause severe dermal irritation or has a pH of <2 or >11.5
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual observations for entire day of dosing
10. Individual observations for entire day of dosing and individual daily observations afterwards, until eyes are normal or for 21 days
11. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of $\leq$ 2 or $\geq$ 11.5.
3.* ____ 6 adult animals.
4. ____ Dosing, single dermal.
5. ____ Dosing duration 4 hours.
6. ____ Application site shaved or clipped at least 24 hour prior to dosing.
7. ____ Application site approximately 6 cm^2.
8. ____ Application site covered with a gauze patch held in place with nonirritating tape
9. ____ Material removed, washed with water, without trauma to application site
10. ____ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.* ____ Individual observations for the entire day of dosing.
12.* ____ Individual daily observations.

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

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD-50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for entire day of dosing.
12. Individual observations for entire day of dosing and individual daily observations thereafter
13. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of $\leq$ 2 or $\geq$ 11.5.
3. ____ One of the following methods is utilized;
   - ____ Freund's complete adjuvant test
   - ____ Guinea pig maximization test
   - ____ Split adjuvant technique
   - ____ Buehler test
   - ____ Open epicutaneous test
   - ____ Mauer optimization test
   - ____ Footpad technique in guinea pig
   - ____ Other test accepted by OECD (specify)_____
4. ____ Complete description of test
5.* ____ Reference for test.
6. ____ Test followed essentially as described in reference document.
7.* ____ Positive control included.

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

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive or has pH <2 or >11.5).
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

ATTACHMENT G

LIST OF ALL REGISTRANT(S) SENT THIS DATA CALL-IN NOTICE

Case Number and Name

0011 Warfarin & its Na salt

Chemical Number and Name

086002 3-(alpha-acetonylbenzyl)-4-hydroxycoumarin

Company Number	Company Name	Additional Name	Address	City & State	Zip
000407	IMPERIAL INC		BOX 98	SHENANDOAH IA	51601
000584	JACK M. CLARK, INC.		BOX 566	HUSTONTOWN PA	17229
000602	PURINA MILLS, INC.		BOX 66812	ST LOUIS MO	63166
000655	PRENTISS DRUG & CHEMICAL COMPANY IN		21 VERNON ST._C.B. 2000	FLORAL PARK NY	11001
000690	PERK PRODUCTS AND CHEMICAL CO., INC		BOX 100585	NASHVILLE, TN	37210
000746	IMPERIAL INC.	AGENT FOR: MFA OIL CO.	BOX 98	SHENANDOAH IA	51601
000995	MACKWIN COMPANY		25 MCCONNON DR.	WINONA MN	55987
001304	FURST MCNESS COMPANY		120 E CLARK ST	FREEPORT IL	61032
002006	GOOD-WAY INSECTICIDE INC		BOX 2768	WHEELING IL	60090
002393	HACO, INC	D/B/A/ HOPKINS AGRICULTURAL CHEMICA	BOX 7190	MADISON WI	53707
002724	ZOECON CORPORATION	A SANDOZ COMPANY	12200 DENTON DRIVE	DALLAS TX	75234
003282	D-CON COMPANY INC		225 SUMMIT AVENUE	MONTVALE NJ	07645
003487	BACON PRODUCTS COMPANY INC		BOX 22187	CHATTANOOGA TN	37422
003536	PIPESTONE PRODUCTS CO. INC.		P.O. BOX 36	TROSKY MN	56177
003941	ATHENA CORPORATION		1919 LONE STAR DR.	DALLAS TX	75212
004271	R & M EXTERM INC		S. 24212 "D" ST.	CHENEY WA	99004
005836	WINDLER PEST CONTROL		116 E 5TH ST	FOWLER IN	47944
005887	WILBUR-ELLIS COMPANY		BOX 9518	FRESNO CA	93792
006383	FERRET LABORATORIES INC.		120 STORCK STREET BOX 437	SLINGER WI	53086
006653	GOULDS DELL PROD		1318 COMMERCE PARK DR	WILLIAM SPORT PA	17701
006720	SOUTHERN MILL CREEK PRODUCTS		5414 NORTH 56TH STREET	TAMPA FL	33610
007122	THE ARCHEM CORP.		1514 ELEVENTH ST	PORTSMOUTH OH	45662
007276	RMC PROD COMPANY		BOX 848	FT DODGE IA	50501
007455	AGRICULTURAL PRODUCTS DIVISION	INTERNATIONAL MULTIFOODS	MULTIFOODS TOWER BOX 2942	MINNEAPOLIS MN	55402
007537	HOBBY'S RAT & MOUSE BAIT, INC.		685 FOREST PARK DR.	BERNE IN	46711
008580	HILLIARD PRODUCTS INC		1453 DIVISION HWY	NEW HOLLAND PA	17557
008845	THE SPECTRUM GROUP DIVISION OF	UNITED INDUSTRIES CORPORATION	BOX 15842	ST LOUIS MO	63114
008848	SAFEGUARD CHEMICAL CORP		806 E. 144 ST.	BRONX NY	10454
009561	KELLEY'S PROFESSIONAL RODENT CONTRO		RT. 3 BOX 86F	EDINBURG TX	78539
010370	FORD'S CHEMICAL AND SERVICE, INC.		2739 PASADENA BLVD.	PASADENA TX	77502
010442	BIDDLE SAWYER CORPORATION		2 PENN PLAZA	NEW YORK NY	10001
012455	PROVORNY, JACOBY & ROBINSON	AGENT FOR: BELL LABORATORIES, INC.	1350 CONNECTICUT AVENUE, N.W., SUIT	WASHINGTON DC	20036
017975	DEAN JERRY EXTERMINATING CO.		307 E. 8TH ST	SPENCER IA	51301
034274	BLUE RIBBON FEED MILL		RT 2	CELINA OH	45822
045722	J.R. CODER CO.		10290 S.E. CINDY LANE	BORING OR	97009
056176	DE & GE PRODUCTS INC		BOX 634	DENISON IA	51442

Case Number and Name

0011 Warfarin & its Na salt

Chemical Number and Name

086003 Warfarin sodium salt

Company Number	Company Name	Additional Name	Address	City & State	Zip
003282	D-CON COMPANY INC		225 SUMMIT AVENUE	MONTVALE NJ	07645
007276	RMC PROD COMPANY		BOX 848	FT DODGE IA	50501
012455	PROVORNY, JACOBY & ROBINSON	AGENT FOR: BELL LABORATORIES, INC.	1350 CONNECTICUT AVENUE, N.W., SUIT	WASHINGTON DC	20036

ATTACHMENT H

COST SHARE AND DATA COMPENSATION FORM FORMS
(FOR GENERIC AND PRODUCT SPECIFIC DATA)
AND
PRODUCT SPECIFIC DATA REPORT FORM

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration 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.

   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)(D) 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:

   _____

   [ ] 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)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

ature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-34 (4-90)

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
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

1. For each study cited in support of registration or reregistration 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 notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay pensation for those data in accordance with sections 3(c)(1)(D) 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)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] 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)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
ame and Title (Please Type or Print)	

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

gnature	Date
m. Title (Please Type or Print)	

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
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number

Chemical Name	EPA Chemical Number

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

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

Typed Title (Please Type or Print)

EPA Form 8570-32 (4-90)