United States Environmental Protection Agency
Office of Pesticide Programs
September 1991

Reregistration Eligibility Decision (RED)

Dried Blood

DRIED BLOOD REREGISTRATION ELIGIBILITY TEAM

Fred Betz	Biologist, Science Analysis and Coordination Staff, Environmental Fate and Effects Division, Office of Pesticide Programs
Rame Cromwell	Review Manager, PM-14, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs
Winston Dang, Ph.D.	Chemist, Occupational and Residential Exposure Branch, Health Effects Division, Office of Pesticide Programs
Ernestine Dobbins	Chemical Review Manager, Accelerated Reregistration Branch, Special Review and Reregistration Division, Office of Pesticide Programs
Robert Forrest	Insecticide-Rodenticide Branch, Product Manager 14, Registration Division, Office of Pesticide Programs
Jean Frane	Policy and Special Projects Staff, Office of Pesticide Programs
Eran Gasko	Office of General Counsel
Bill Gross	Biologist, Biological Analysis Branch, Biological and Economics Analysis Division, Office of Pesticide Programs
Steve Jacobs	Information Management Section, Biological Analysis Branch, Biological and Economics Analysis Division, Office of Pesticide Programs
J. Thomas McClintock, Ph.D.	Microbiologist, Science Analysis and Coordination Branch, Health Effects Division, Office of Pesticide Programs

Brian J. Montague	Fisheries Biologist, Ecological Effects Branch, Environmental Fate and Effects Division, Office of Pesticide Programs
Christine E. Rice	Section Chief, Accelerated Reregistration Branch, Special Review and Reregistration Division, Office of Pesticide Programs
Beverly Updike	Office of Compliance Monitoring, Office of Pesticide Programs

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EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) first registered a pesticide product containing dried blood in 1958. This product also contained napthalene and tobacco dust as active ingredients. Currently, dried blood is registered in three end-use products as rabbit and dog repellents. These products are dust formulations for use around ornamental plants, trees, and shrubs. None of the three registered products contain dried blood as a single active ingredient, but in combination with either napthalene and tobacco dust or napthalene and thiram. This document focuses only on dried blood.

The data base to support the reregistration of dried blood is sufficient to allow the Agency to conduct reasonable risk assessments for registered uses of dried blood. These data support the Agency conclusion that the uses of dried blood will not result in unreasonable public health risks or effects to the environment. Therefore, EPA has determined that all products containing dried blood as an active ingredient are eligible for reregistration.

Before reregistering each product, the Agency is requiring product specific data to be submitted within eight months from the issuance of this document. After reviewing these data and the revised labels, EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met for each product. The product will be reregistered if its composition and labeling are acceptable, and its uses will not cause unreasonable adverse effects to humans or the environment. End-use products containing dried blood 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.

I. INTRODUCTION

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

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

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

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

II. ACTIVE INGREDIENT COVERED BY THIS REREGISTRATION ELIGIBILITY DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

Chemical Name: Blood, glyoxal-denatured, dried (referred to hereafter as dried blood)

Common Name: dried blood

CAS Number: 68911-49-9

Office of Pesticide Programs Chemical Code Number: 00611

Empirical Formula: Not applicable for dried blood.

Trade Names: None

Basic Sources: Cattle slaughter houses

B. USE PROFILE

Type of Pesticide: biochemical pesticide, animal repellent

Pests Repelled: rabbits, dogs

Registered Use Sites:

Terrestrial Non-Food - ornamental plants, trees, and shrubs.

Residential Outdoor - ornamental plants, trees, and shrubs.

Formulation Types Registered: Dust - 5.0%
15.0%

Method of Application: Spread 6 to 8 inches away from plant or tree. Apply a 2" wide band around the plants to be protected or up and down rows. Wet well so that it will adhere to the soil. Wear gloves during application. Repeat applications about every two weeks.

C. REGULATORY HISTORY

In 1958, the Agency first registered a pesticide product with dried blood as an active ingredient in combination with napthalene and tobacco Dust. This product, a dog and rabbit repellent under the name F & B Rabbit and Dog Chaser, is currently registered. As indicated ina previous Section, dried blood is registered in two other end-use products as rabbit and dog repellents. These products are dust formulations for use around ornamental plants, trees, and shrubs. All three registered products contain dried blood in combination with either napthalene and tobacco dust or napthalene and thiram.

Until recently, dried blood was classified by the Agency as a conventional chemical pesticide. Now the Agency has reclassified the subject compound as a biochemical pesticide because it is a naturally occurring substance and because it has a non-toxic mode of action. The source of this dried blood is from the slaughter houses of cattle.

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

A. INGREDIENT DESCRIPTION

Dried blood, or blood meal, is produced from clean fresh cattle (beef) blood. Blood meal is a highly proteinaceous compound (91%) which contains approximately 14% nitrogen, less than 0.1% phosphorus and potassium, and trace amounts of iron.[2]

During the manufacturing process considerable care is taken to ensure that the product is devoid of hair, regurgitant, and urine. Briefly, the fresh raw blood is collected from cattle at the slaughter house and ring dried (same as flash dried) by heating with saturated steam. The blood is centrifuged to a coarse wet powder (less than or equal to 60% moisture) and passed through a "blood dryer" which brings the blood into direct contact with hot air steam for further drying. The blood is heated for 25 minutes at a temperature range of 200 to 1,000^{o}F, the dried blood powder is removed from the drum, collected and bagged or shipped for further processing. The final product is highly insoluble in water with a stability of greater than one year without loss of nitrogen content. [2]

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[2] See Bibliography Reference 1.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Data Base

Since the manufacturing process ensures complete denaturation of proteinaceous material and inactivation of specific and potential mammalian pathogens (i.e., endogenous or exogenous contaminants) all toxicological data requirements normally required under 40 Code of Federal Regulations, Part 158, for the use patterns of the registered products have been waived. Consequently, since all toxicology requirements have been waived, specific toxicity values do not apply and no further generic data are being required.

2. Applicator Exposure

During application of currently registered products, the Agency expects there may be some potential for dermal and inhalation exposure. However, any post-application exposure is expected to be low since the products are applied directly to the ground. The Agency believes that the dried blood in the products poses no known human risks, but current labels require the use of gloves in order to reduce exposure to the other active ingredients (naphthalene, tobacco dust, or thiram). Product labeling requirements will be reevaluated considering the other active ingredients in the products before individual products are reregistered.

Based on the lack of toxicological concerns for dried blood, there are no additional exposure data or product labeling requirements at this time.

3. Human Risk Assessment

As addressed in III.A and B.2 above, the potential risks, if any, to humans from application exposure, are considered negligible because: (1) the manufacturing process ensures denaturation of proteinaceous material and inactivation of potential pathogens, (2) the lack of toxicological concerns associated with dried blood, and (3) the probable low exposure to applicators. Therefore, the Agency concludes that there are no adverse effects associated with the active ingredient dried blood.

C. ENVIRONMENTAL ASSESSMENT

The basic data requirements for a biochemical pesticide consist of the Tier I ecological effects studies. Environmental fate (Tier II) and additional ecological effects (Tier III) studies are not required for biochemical pesticides unless adverse effects are observed in Tier I studies. As described below, the Tier I studies have been waived for dried blood.

1. ECOLOGICAL EFFECTS DATA

Waivers have been granted for dried blood for all ecological effects studies normally required by the Agency for pesticides with these use patterns. The basis for this is as follows: (1) there is no evidence in the available information that demonstrates or suggests any hazards to the environment (nontarget organisms) when dried blood is used as directed; (2) the use pattern involves manual application of spot and band treatments in residential areas and therefore, exposure of nontarget organisms should be negligible; (3) the manufacturing process (as summarized in III.A.) ensures that potential pathogens are inactivated and that proteinaceous material is denatured; (4) dried blood is a naturally occurring substance; and (5) dried blood acts as a repellent rather than a toxicant.

2. ENVIRONMENTAL FATE DATA

Because dried blood is a biochemical pesticide, the requirement for environmental fate data is contingent upon the results of Tier I ecological effects data requirements. Since there are no ecological effects concerns with the specified use of dried blood, there are no environmental fate data requirements.

The Agency does not foresee the potential for significant risks associated with the specified use of dried blood. No hazard or exposure issues have been identified that need to be addressed further. Therefore, no ecological effects or environmental fata data are required to support the reregistration of dried blood.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required or waived the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing dried blood 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 dried blood. Appendix B identifies the data requirements that the Agency reviewed as part of its determination of reregistration eligibility of dried blood.

The data identified above is sufficient to allow the Agency to conduct a reasonable risk assessment for the registered uses of dried blood. The data the Agency has supports the conclusion that the use of dried blood will not result in unreasonable effects to humans or the environment. The Agency therefore finds that all products containing dried blood as an active ingredient for the specified use patterns are eligible for reregistration (See Appendix A for use patterns). The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

Although the Agency has found that products containing dried blood 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 reregistration of products containing dried blood, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on consideration of information about the active ingredient dried blood and the registered use patterns, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

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

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING DRIED BLOOD

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

2. Based on consideration of information about dried blood and the product uses:

There are no additional label requirements at this time.

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION

FOR

DRIED BLOOD

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR DRIED BLOOD

SITE Application Type, Application Timing, Application Equipment (Formulation)	Max Application Rate (active ingredient)	Max # Apps	Max # Apps @ Max Rate	Min. Interval Between Apps @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limits	Use Limitations
ORNAMENTAL HERBACEOUS PLANTS							
Band treatment, When needed, None specified (Dust)	3 lb ai/2 in by 85 linear ft	Not spec	Not spec	As Needed	None	None	
Band treatment, When needed, With glove (Dust)	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	
ORNAMENTAL LAWNS AND TURF							
Band treatment, When needed, With glove (Dust)	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	
ORNAMENTAL WOODY SHRUBS & VINES							
Band treatment, When needed, None specified (Dust)	3 lb ai/2 in by 85 linear ft	Not spec	Not spec	As Needed	None	None	
Band treatment, When needed, With glove (Dust)	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	
ORNAMENTAL AND/OR SHADE TREES							
Band treatment, When needed, None specified (Dust)	3 lb ai/2 in by 85 linear ft	Not spec	Not spec	As Needed	None	None	
Band treatment, When needed, With glove (Dust)	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES							
Band treatment, When needed, None specified (Dust)	3 lb ai/2 in by 85 linear ft	Not spec	Not spec	As Needed	None	None	
Band treatment, When needed, With glove (Dust)	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	

SITE Application Type, Application Timing, Application Equipment (Formulation)	Max Application Rate (active ingredient)	Max # Apps	Max # Apps @ Max Rate	Min. Interval Between Apps @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limits	Use Limitations
FENCEROWS. **Band treatment, When needed, With glove (Dust)**	3 lb ai/2 in by 100 linear ft	Not spec	Not spec	14	None	None	

Abbreviations Used

ai = active ingredient; Apps = Applications; Max = Maximum; Not spec = Not specified; in = inches; ft = feet

APPENDIX B

Generic Data Requirements for Reregistration of Dried Blood Supporting Reregistration

GUIDE TO APPENDIX B

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

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

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

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

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

C Terrestrial non-food
K 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 B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
151B-10	Product Identification	CK	Data were obtained from the most recent confidential statements of formula for registered products.
151B-11	Manufacturing Process	CK	1
151B-12	Discussion of Formulation of Unintentional Ingredients	CK	1
151B-13	Analysis of Samples	CK	1
151B-15	Certification of Limits	CK	1
151B-16	Analytical Methods	CK	1

1 Information was obtained from internal files and documents.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry: (continued)			
151B-17(a)	Color	CK	1
151B-17(b)	Physical State	CK	1
151B-17(c)	Odor	CK	1
151B-17(e)	Boiling Point	CK	1
151B-17(f)	Density or Specific Gravity	CK	1
151B-17(g)	Solubility	CK	1
151B-17(h)	Vapor Pressure	CK	1
151B-17(i)	pH	CK	1
151B-17(j)	Stability	CK	1
151B-17(k)	Flammability	CK	Not applicable

151B-17(l)	Storage Stability	CK	1
151B-17(m)	Viscosity	CK	Waived

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GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
151B-17(n)	Miscibility	CK	Waived
151B-17(o)	Corrosion Characteristics	CK	Waived
151B-17(p)	Octanol/H_20 Partition Coefficient	CK	Waived

1 Information was obtained from internal files and documents.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Ecological Effects			
154-6	Avian Acute Oral	CK	Waived
154-7	Avian Dietary	CK	Waived
154-8	Freshwater Fish LC50	CK	Waived
154-9	Freshwater Invertebrate LC50	CK	Waived

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GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology:			
152B-10	Acute Oral Toxicity	CK	Waived
152B-11	Acute Dermal Toxicity	CK	Waived
152B-12	Acute Inhalation	CK	Waived
152B-13	Primary Eye Irritation	CK	Waived
152B-14	Primary Dermal Irritation	CK	Waived
152B-15	Dermal Sensitization	CK	Waived
152B-16	Hypersensitivity*	CK	Waived
152B-18	Immunotoxicity	CK	Waived

* Any incidents of hypersensitivity must be reported to the Agency.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
152B-20	90-Day Feeding (1 Species)	CK	Waived
152B-21	90-Day Dermal-Rat	CK	Waived
152B-22	90-Day Inhalation-Rat	CK	Waived
152B-23	Teratogenicity (1 Species)	CK	Waived
152B-17	Mutagenicity (Ames)	CK	Waived

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF DRIED BLOOD AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Environmental Fate			
Data requirements do not apply since ecological effects data are waived.			

APPENDIX C

DRIED BLOOD BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

Chemical Name: Dried Blood

1. Letter from Bart Edsell, Taylor By-Products, dated May 23, 1991, providing the Process Description and Statement of Sterilization for dried blood.

Aside from reference 1 above, there are no other bibliographic citations for dried blood. All other references were taken from internal files and documents.