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EPA

Reregistration Eligibility Document (RED)

Putrescent Whole Egg Solids

REREGISTRATION ELIGIBILITY DOCUMENT

PUTRESCENT WHOLE EGG SOLIDS

LIST D

CASE 4079

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

This Reregistration Eligibility Document (RED) addresses pesticide uses of putrescent whole egg solids. Products that contain putrescent whole egg solids are currently registered for use as a repellent in conifer nurseries, open greenhouses, established forestry plantations, ornamental woody shrubs and almond, fruit and citrus orchards. All products that contain putrescent whole egg solids as an active ingredient and that are registered for these uses are eligible for reregistration.

The U.S. Environmental Protection Agency (EPA) has conducted a review of the scientific data base and other relevant information supporting the reregistration of putrescent whole egg solids and has determined that the data base is sufficient to allow the EPA to conduct a risk assessment. All applicable toxicology, ecological and environmental effect data requirements have been waived for this active ingredient. However, EPA believes other available information is sufficient to conclude that the currently registered uses of putrescent whole egg solids will not result in unreasonable adverse effects to human health or the environment. Putrescent whole egg solids is exempt from the requirement of a tolerance when used as an animal repellent in almond orchards (40 CFR part 180.1071).

Accordingly, EPA has determined that all products containing putrescent whole egg solids as the active ingredient are eligible for reregistration and will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, EPA is requiring that product specific data and revised labeling be submitted by the registrants within eight months of the issuance of this document. In an effort to reduce the time, resources, and number of animals needed to fulfill the acute toxicology data requirements for putrescent whole egg solids containing end use products, EPA has attempted to "batch" products considered to be similar with respect to acute toxicity testing requirements. However, this was not possible, so the registrant must individually satisfy the data requirements for each of their products. After reviewing these data and the revised labels, EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met EPA will reregister the product. Any end-use products containing putrescent whole egg solids in combination with other active ingredients will not be reregistered until the REDs for all active ingredients contained in that product are issued.

I. INTRODUCTION

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

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products, section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," sections 4(g)(2)(C) and (D). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA 3(c)(5).

This document presents the EPA's decision regarding the reregistration eligibility of the active ingredient putrescent whole egg solids. The document consists of five sections. Section I is this introduction. Section II describes putrescent whole egg solids, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to EPA. Section IV discusses the reregistration eligibility decision for putrescent whole egg solids and Section V discusses product reregistration requirements. Additional details concerning the 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. CASE OVERVIEW

A. Chemical Overview

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

Chemical Name: Putrescent Whole Egg Solids

CAS Number: 51609-52-0

Office of Pesticide Programs Chemical Code: 105101

B. Use Profile

The following is information on the registered use with specific use sites and application methods. A detailed table of eligible uses of putrescent whole egg solids is in Appendix A.

Type of Pesticide: Repellent or Feeding Depressant

Pests: Black- and White-Tailed Deer, Roosevelt Elk and Mountain Beaver

Use Sites: Terrestrial Food/Feed Crop: almond - not to be used within 30 days of harvest, and fruit and citrus orchards (unspecified) - use only when trees are dormant.

Terrestrial Non-Food Crop: ornamental and/or shade trees, ornamental woody shrubs and vines, established forestry plantations and conifer seedlings.

Greenhouse Non-Food Crop: ornamental and/or shade trees.

Outdoor Residential: ornamental and/or shade trees and ornamental woody shrubs and vines.

Formulation Types Registered:	End-use
Form:	Dust at 36% active ingredient (a.i.) Liquid - Ready to Use (RTU) at 5% a.i. Emulsifiable Concentrate at 15% and 37% a.i.
Methods of Application:	Dust: The dust is applied to moist plants using a shaker duster to apply a light coating of the dust on the target plants. If dry, the plants must be wetted. Liquid: In nurseries or large greenhouses spray mixtures are applied to runoff to ensure coverage of the target seedlings. For established forestry plantations, ornamental woody shrubs, almond, fruit, and citrus orchards a pressurized hand-held or back-pack garden sprayer is used and foliage is sprayed to achieve runoff. For large trees spray is applied to lateral branches that are potentially within the animals' reach.

C. REGULATORY HISTORY

EPA registered the first putrescent whole egg solid-containing product on September 8, 1975. The currently registered products are used as repellents in the sites identified in Section II. B. above. In 1985 EPA exempted putrescent whole egg solids from the requirement of a tolerance when used as an animal repellent in almond orchards (40 CFR 180.1071). Fresh eggs and egg products are Generally Recognized As Safe (GRAS) (21 CFR 170.3), by FDA.

III. SCIENCE ASSESSMENT OF PUTRESCENT WHOLE EGG SOLIDS

EPA has reviewed the scientific data base for putrescent whole egg solids relying on information submitted by the registrant. These are cited in Appendix C.

A. PRODUCT CHEMISTRY ASSESSMENT

Putrescent whole egg solids (inedible egg powder, dried whole egg, or powdered inedible egg solids), are produced from eggs which the USDA has declared inedible for human consumption due to cracked shells, excessive blood spots or other imperfections not conforming to standards set for food use. The final product is highly proteinaceous (50-55%) containing fat (28-34%), vitamins and minerals.

Putrescent whole egg solids are produced by centrifuging whole eggs (cracked or broken) to separate the shell from the liquid egg. The liquid egg is pumped through a strainer to remove foreign material (shell pieces) then placed in a holding tank or passed through a pasteurizer. Following pasteurization, the liquid is cooled, spray dried, bagged and stored until shipping. At the time of use, the powdered eggs are hydrated which initiates the decaying process. This is repugnant and acts to repel the target pests.

Quality control procedures include testing for total protein, fat and solid content, nutritional composition and for the presence or absence of Salmonella (standard requires complete absence), yeast and mold (standard requires less than 10 CFU/gm), and coliforms (standard requires less than 10 CFU/gm).

Putrescent whole egg solids have a faint orange to beige color with a slightly malty odor. The physical state of this material is described as a powder mixture of fine particles and loosely packed aggregates. Putrescent whole egg solids are insoluble in water, petroleum distillate, isopropanol and 1,1,1-trichloroethane. The bulk density is calculated to be 0.514 gm/ml and the pH is 6.4 (10% solution of dried whole egg in water).

B. Enviromental and Human Health Assessment

EPA has developed a normative set of data requirements, set forth in the regulations (40 CFR part 158) and the Agency's Reregistration Phase 2 Technical Guidance Document. These data requirements must be addressed for pesticide reregistration. These regulations and the guidance document specify the necessary data based on such factors including use sites, potential environmental and human (dietary and occupational) exposures, product formulation types, product application methods, and results of initial (Tier 1) studies. Due to the diverse nature and characteristics of pesticide products and their uses subject to reregistration, the Agency also recognizes the need to modify the data requirements for specific

pesticides, including waiving certain data requirements, because such requirements are inappropriate or unnecessary for reregistration.

The case-specific approach to waive individual data requirements has served to identify the appropriate data requirement sets for pesticide products. Further, the Agency believes there is a category of pesticide active ingredients for which a broadly reduced set of data requirements are appropriate for reregistration. Specifically, products in this category would be exempt from the generic data requirements for toxicology, residue chemistry, human exposure, ecological effects, and environmental fate on the active ingredient. The Agency believes there are numerous considerations which, when taken together, can form the basis for a conclusion that such a reduction in data requirements is appropriate for a particular pesticide active ingredient, while not compromising human health or environmental safety.

There are, however, certain data requirements which are essential and may not be waived. Basic chemistry data on the active ingredient and formulated products are required for pesticides in this category so that the Agency has reasonable certainty of the pesticide's identity and chemical/physical characteristics. Also, acute toxicology studies for formulated products are required for the Agency to determine appropriate product labeling for potential hazards to those who handle or apply such products. However, these toxicology studies may be waived if an assessment of the product formulation, including the inert ingredients, indicates that such studies are unnecessary to determine appropriate labeling.

In considering putrescent whole egg solids for reregistration eligibility, the Agency believes it is an active ingredient that should be considered for this broad waiver of the generic data requirements. The considerations that lead the Agency to this conclusion are as follows:

Fresh eggs and egg products are Generally Recognized As Safe (GRAS) (21 CFR 170.3), by FDA. Egg solids are also recognized as a common human food or significant component of a common human food.

No reports of adverse effects have been submitted to the Agency for this active ingredient. There is no indication of any other significant adverse effects from putrescent whole egg solids to humans or the environment associated with its use as a pesticide.

This pesticide is used as a repellent in conifer nurseries, open greenhouses, established forestry plantations, ornamental woody shrubs, almond, fruit, and citrus orchards. The active ingredient putrescent whole egg solids has a non-toxic mode of action for its target pest. This pesticide can be presumed non-persistent based on knowledge of its composition. The egg solids' organic material is known to degrade rapidly in the environment to elemental constituents by normal biological, physical

and/or chemical processes that can be reasonably expected to exist where the pesticide is applied.

Based on these factors the Agency does not believe generic data, beyond those data required to satisfy basic product identity and chemistry questions (refer to Appendix B), are necessary to determine if the current registered uses of this active ingredient pose unreasonable risks to humans or the environment. Therefore, EPA is not requiring the submission of additional generic data for the active ingredient putrescent whole egg solids. However, EPA is requiring the submission of product specific data (product chemistry, acute toxicity and efficacy). The Agency believes that, based on the above factors, the uses of registered products containing putrescent whole egg solids do not pose unreasonable risks to humans or the environment.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR PUTRESCENT WHOLE EGG SOLIDS

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA requires the Agency to determine, after consideration of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. For products containing putrescent whole egg solids as an active ingredient the Agency waived all generic data requirements except those for basic product identity and chemistry. These data were submitted and reviewed. In addition to these data the Agency has considered the factors discussed above in Section III, regarding the natural occurrence of putrescent whole egg solids, common use as a food item, and the lack of reported adverse effects information. The Agency has completed its consideration of these data and other factors and has determined this information is sufficient to support reregistration of products containing putrescent whole egg solids as an active ingredient. The reregistration of particular products is addressed in Section V. of this document.

Although the Agency has concluded that products containing putrescent whole egg solids are eligible for reregistration, the Agency may take regulatory actions in the future that would affect the continued registration of putrescent whole egg solid-containing products if significant information about this active ingredient and/or its products comes to the Agency's attention. Such regulatory action could include requiring the submission of additional data if the data requirements for registration (or the guidelines for generating such data) change.

B. Additional Generic Data Requirements

The generic data base supporting the reregistration of products containing putrescent whole egg solids has been reviewed and determined to be substantially complete for reregistration.

C. Labeling Requirements for Manufacturing-Use Products of Putrescent Whole Egg Solids

There are no manufacturing-use products registered.

V. ACTIONS REQUIRED BY REGISTRANTS OF END-USE PRODUCTS

A. Determination of Eligibility

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

1. Product Specific Data Requirements

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

2. Labeling Requirements for End-Use Products Containing Putrescent Whole Egg Solids

The labels and labeling of all products must comply with EPA's current regulations and requirements. Instructions to comply with these requirements are contained in the Product Reregistration Handbook.

APPENDIX A

Putrescent Whole Egg Solids Use Patterns Subject to Reregistration

Appendix A - CASE 4079, (Putrescent whole egg solids) Chemical 105101 (Putrescent whole egg solids)

SITE APPLICATION TYPE, APPLICATION TIMING, APPLICATION EQUIPMENT	FORM	MIN. APP. RATE	MAX. APP. RATE	MAX. # APPS	MAX # APPS. @ MAX. RATE	MIN. INTERVAL BETWEEN APPS. (DAYS)	RESTRICTED ENTRY INTERVAL (DAYS)	GEOGRAPHIC ALLOWED	GEOGRAPHIC DISALLOWED	USE LIMITATIONS (CODES)
ELIGIBLE FOR REREGISTRATION										
FOOD/FEED USES										
ALMOND	Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust., Foliar., Duster.	D	NA	NA	NS	NS	NS	NS			H01(30)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	DCNC	NS	NS	NS	NS			H01(30)
CITRUS FRUITS	Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust., Foliar., Duster.	D	NA	NA	NS	NS	NS	NS			
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	DCNC	NS	NS	NS	NS			
ORCHARDS (UNSPECIFIED)	Use Group: TERRESTRIAL FOOD+FEED CROP									
Dust., Foliar., Duster.	D	NA	NA	NS	NS	NS	NS			
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	DCNC	NS	NS	NS	NS			
NON FOOD/NON-FEED										
CITRUS FRUITS	Use Group: TERRESTRIAL NON-FOOD CROP									
Dust., Nonbearing., Duster.	D	NA	NA	NS	NS	NS	NS			
Low volume spray (concentrate)., Nonbearing., Low volume ground.	EC	NA	DCNC	NS	NS	NS	NS			
ORCHARDS (UNSPECIFIED)	Use Group: TERRESTRIAL NON-FOOD CROP									
Dust., Nonbearing., Duster.	D	NA	NA	NS	NS	NS	NS			
Low volume spray (concentrate)., Nonbearing., Low volume ground.	EC	NA	DCNC	NS	NS	NS	NS			
Spray., Nonbearing., Sprayer.	SC/L	NA	DCNC	NS	NS	AW	NS			
ORNAMENTAL AND/OR SHADE TREES	Use Group: GREENHOUSE NON-FOOD CROP									
Spray., Dormant., Pressurized tank sprayer.	EC	NA	DCNC	NS	NS	AW	NS			
	SC/L	NA	DCNC	NS	NS	AW	NS			
ORNAMENTAL AND/OR SHADE TREES	Use Group: TERRESTRIAL NON-FOOD CROP									
Dust., Nurserystock., Duster.	D	NA	NA	NS	NS	NS	NS	OR		
	D	NA	NA	NS	NS	NS	NS			
Dust., Seedling stage., Duster.	D	NA	NA	NS	NS	NS	NS	OR		
	D	NA	NA	NS	NS	NS	NS			
Dust., Whorl., Duster.	D	NA	DCNC	NS	NS	NS	NS	OR		
	D	NA	DCNC	NS	NS	NS	NS			
Spray., Nurserystock., Pressurized tank sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
	SC/L	NA	DCNC	NS	NS	NS	NS			
Spray., Seedling stage., Backpack sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
	RTU	NA	DCNC	NS	NS	NS	NS			
	SC/L	NA	DCNC	NS	NS	NS	NS			
Spray., Seedling stage., Hand held sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
	RTU	NA	DCNC	NS	NS	NS	NS			
	SC/L	NA	DCNC	NS	NS	NS	NS			
Spray., Whorl., Backpack sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
	RTU	NA	DCNC	NS	NS	NS	NS			
	SC/L	NA	DCNC	NS	NS	NS	NS			
Spray., Whorl., Hand held sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
	RTU	NA	DCNC	NS	NS	NS	NS			
	SC/L	NA	DCNC	NS	NS	NS	NS			
ORNAMENTAL AND/OR SHADE TREES	Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Dust., Dormant., Duster.	D	NA	NA	NS	NS	NS	NS	OR		
Dust., Foliar., Duster.	D	NA	NA	NS	NS	NS	NS			
Dust., Seedling stage., Not on label.	D	NA	NA	NS	NS	NS	NS	UA		
Spray., Dormant., Sprayer.	SC/L	NA	DCNC	NS	NS	AW	NS			
Spray., Foliar., Sprayer.	EC	NA	DCNC	NS	NS	AW	NS			
ORNAMENTAL WOODY SHRUBS AND VINES	Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Dust., Dormant., Duster.	D	NA	NA	NS	NS	NS	NS	OR		

Appendix A - CASE 4079, (Putrescent whole egg solids) Chemical 109101 (Putrescent whole egg solids)

SITE APPLICATION TYPE, APPLICATION TIMING, APPLICATION EQUIPMENT	FORM	MIN. APP. RATE	MAX. APP. RATE	MAX. # APPS	MAX. # APPS. @ MAX. RATE	MIN. INTERVAL BETWEEN APPS. (DAYS)	RESTRICTED ENTRY INTERVAL (DAYS)	GEOGRAPHIC ALLOWED	GEOGRAPHIC DISALLOWED	USE LIMITATIONS (CODES)
NON FOOD/NON-FEED (con't)										
ORNAMENTAL WOODY SHRUBS AND VINES	Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)									
Dust., Foliar., Duster.	D	NA	NA	NS	NS	NS	NS			
Spray., Dormant., Sprayer.	SC/L	NA	DCNC	NS	NS	AN	NS			
Spray., Foliar., Sprayer.	EC	NA	DCNC	NS	NS	NS	NS			
URBAN AREAS	Use Group: TERRESTRIAL NON-FOOD CROP									
Animal burrow treatment., When needed., Not on label.	D	NA	NA	NS	NS	NS	NS	OR		
	D	NA	NA	NS	NS	NS	NS	WA		

LEGEND

== HEADER ABBREVIATIONS

MIN. APP. RATE : MINIMUM APPLICATION RATE

MAX. APP. RATE : MAXIMUM APPLICATION RATE

MIN. INTERVAL BETWEEN APPS. (DAYS) : MINIMUM INTERVAL BETWEEN APPLICATIONS (DAYS)

MAX # APPS : MAXIMUM NUMBER OF APPLICATION

MAX. # APPS. @ MAX. RATE : MAXIMUM NUMBER OF APPLICATION AT MAXIMUM DOSAGE RATE

== ABBREVIATIONS

NS : NOT SPECIFIED (ON LABEL)

NA : NOT APPLICABLE

AN : AS NEEDED

== MAXIMUM APPLICATION RATE

DCNC : DOSAGE CAN NOT BE CALCULATED

== USE LIMITATIONS CODES

NOI :__ daytal preharvest interval.

* NUMBER IN PARENTHESES REPRESENTS NUMBER OF "DAYS"

== FORMULATION CODES

D :DUST

EC :EMULSIFIABLE CONCENTRATE

SC/L :SOLUBLE CONCENTRATE/LIQUID

RTU :LIQUID-READY TO USE

== GEOGRAPHIC CODES

OR : OREGON

WA : WASHINGTON

APPENDIX B

Generic Data Requirements for Putrescent Whole Egg Solids and Data Citations Supporting Reregistration

GUIDE TO APPENDIX B

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

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

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

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

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

APPENDIX B

Generic Data Supporting Guideline Requirements for Reregistration of Putrescent Whole Egg Solid

Requirement		Putrescent Whole Egg Solids Citation
PRODUCT CHEMISTRY		
151B-10	Product Identity	42072101
151B-11	Manufacturing Process	42072101
151B-12	Discussion of Formation of Unintentional Ingredients	42072101
151B-13	Analysis of Samples	42072102
151B-15	Certification of Limits	42072102
151B-16	Analytical Methods	42072102
151B-17(a)	Color	42072103
151B-17(b)	Physical State	42072103
151B-17(c)	Odor	42072103
151B-17(d)	Melting Point	42072103
151B-17(f)	Density	42072103
151B-17(g)	Solubility	42072103
151B-17(h)	Vapor Pressure	42072103
151B-17(i)	pH	42072103
151B-17(j)	Stability	42072103
151B-17(p)	Octanol/Water Partition Coefficient	42072103

APPENDIX B

Generic Data Supporting Guideline Requirements for Reregistration of Putrescent Whole Egg Solids

Requirement		Putrescent Whole Egg Solids Citation
TOXICOLOGY		
152B-10	Acute Oral Toxicity in the Rat	42019401
152B-11	Acute Dermal Toxicity	42019402
152B-13	Primary Eye Irritation in the Rabbit	42019403
152B-14	Primary Dermal Irritation	42019404
152B-15	Dermal Sensitization	42019405

ECOLOGICAL EFFECTS

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

ENVIRONMENTAL FATE

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

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

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Putrescent Whole Egg Solids

GUIDE TO APPENDIX C

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

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the EPA the EPA has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The EPA has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

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

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

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

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

c. Title. In some cases, it has been necessary for EPA bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the EPA in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

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

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

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

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
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(2) 42019402 Gabriel, D. (1991) Inedible Whole Egg Solids: Acute Dermal Toxicity, Single Level - Rabbits: Lab Project Number: 91-7279A. Unpublished study prepared by Biosearch Inc. 12 p.

(3) 42019403 Bielucke, J. (1991) Inedible Whole Egg Solids: Primary Eye Irritation - Rabbits: Lab Project Number: 91-7279A. Unpublished study prepared by Biosearch Inc. 13p.

(4) 42019404 Romanelli, P. (1991) Inedible Whole Egg Solids: Primary Skin Irritation - Rabbits: Lab Project Number: 91-7279A. Unpublished study prepared by Biosearch Inc. 9 p.

(5) 42019405 Romanelli, P. (1991) Inedible Whole Egg Solids: Guinea Pig Dermal Sensitization - Modified Buehler Method: Lab Project Number: 91-7279A. Unpublished study prepared by Biosearch Inc. 20p.

(6) 42072101 Meinen, V. (1991) Product Identity and Composition of Inedible Dried Whole Egg. Unpublished study prepared by MGK Co. 27 p.

(7) 42072102 Meinen, V. (1991) Analysis and Certification of Product Ingredients for Inedible Dried Whole Egg. Unpublished study prepared by MGK Co. 12 p.

(8) 42072103 Meinen, V. (1991) Product Chemistry of Inedible Dried Whole Egg (Physical and Chemical Characteristics): Lab Project Number: 333-334. Unpublished study prepared by MGK Co. 13 p.

APPENDIX D

PR Notice 91-2

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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

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The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. "COMPLIANCE SCHEDULE," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be set based on representative sampling and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient statements must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentration" on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX E

Pesticide Reregistration Handbook

THE HANDBOOK IS NOT INCLUDED IN THIS COPY OF THE DOCUMENT

APPENDIX F

Product Specific Data Call-in

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

DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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 product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

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

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

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

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

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).

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

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment C, 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 C, 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 product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting

your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you 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. 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 and Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). 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.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you 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.

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

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

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

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

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

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

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been

unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. 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 (Attachment E) and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 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 all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency will 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 if 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 if 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 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 (if applicable), 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 <u>EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS</u>

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 a 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) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment B and Attachment C) 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 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,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

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

ATTACHMENT A

CHEMICAL STATUS SHEET

ATTACHMENT A

PUTRESCENT WHOLE EGG SOLIDS: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing putrescent whole egg solids.

This attachment, the Data Call-in Chemical Status Sheet, contains a 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, (3) Attachment C, the Requirement Status and Registrant's Response Form for product specific data, (4) Attachment D, EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration, (5) Attachment E, EPA Acceptance Criteria, (6) Attachment F, List of All Registrant(s) sent this Data Call-In Notice, and (7) Attachment G, the Cost Share and Data Compensation Forms for product specific data, and Product Specific Data Report Form for use in replying to this putrescent whole egg solids Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for putrescent whole egg solids are listed in the Requirements Status and Registrant's Response Form, Attachment C.

The Agency has concluded that product specific data are needed for putrescent whole egg solids. The required additional data are listed in Attachment C.

Depending on the results of the studies required in this Notice, additional testing may be required.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Rob Forrest at (703) 305-6600. All responses to this Notice should be submitted to:

Document Processing Desk (RED/RD/PM-14)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Putrescent Whole Egg Solids

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Thomas Myers at (703) 308-8074. All responses to this Notice should be submitted to:

Chemical Review Manager Thomas Myers
Accelerated Reregistration Branch (H7508W)
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Putrescent Whole Egg Solids

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

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.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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 (MP) or 7b (EP) 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 (MP) 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 (EP) 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.

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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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 a[illegible] I agree to satisfy the EUP requirements on the attac[illegible] form entitled "Requirement[illegible] Status and Registrant's Response."
4866-8		N.A.	N.A.		

8. Certification	9. Date
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_____	
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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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 IUP and I agree to satisfy the IUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
4866-9		N.A.	N.A.		

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

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OMB No. 2070-0107
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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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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."
4866-10		N.A.	N.A.		

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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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 TUP and I agree to satisfy the TUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
4866-11		N.A.	N.A.		

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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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."
OR88001100		N.A.	N.A.		

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
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids	PRODUCT SPECIFIC

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 a 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 [illegible] and I agree to satisfy the [illegible] requirements on the attached form entitled "Requirements Status and Registrant's Response."
WA88000400		N.A.	N.A.		

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

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS
AND
PR NOTICE 86-5

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.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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 product 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.

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
INTAGRA, INC.
8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. 4866-8

3. Date and Type of OCI
PRODUCT SPECIFIC
ID# 4866-RD-1904

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
151B-17(i)	pH (6)					A C IJK	EP	8 mos.	
151B-17(k)	Flammability (7)					A C IJK	EP	8 mos.	
151B-17(l)	Storage stability					A C IJK	EP	8 mos.	
151B-17(m)	Viscosity (8)					A C IJK	EP	8 mos.	
151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
151B-17(o)	Corrosion characteristics					A C IJK	EP	8 mos.	

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
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INTAGRA, INC.
8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. 4866-8

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1904

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
	Acute Toxic - Biochemical								
152B-10	Acute oral toxicity					A C IJK	EP	8 mos.	
152B-11	Acute dermal toxicity					A C IJK	EP	8 mos.	
152B-12	Acute inhalation (3)					A C IJK	EP	8 mos.	
152B-13	Primary eye irritation					A C IJK	EP	8 mos.	
152B-14	Primary dermal irritation					A C IJK	EP	8 mos.	
152B-15	Dermal sensitization (4)					A C IJK	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					A C IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-19	Browsing animal repellents (50)					A C IJK	EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.(NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.); TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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F - Aquatic nonfood industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: (The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.)

Prod Chem - Biochemical

6 Required if test substance is dispersible with water.
7 Required if product contains combustible liquids.
8 Required if product is a liquid.
9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

3 Required if the product consists of, or under conditions of use results in, an inhalable material (e.g., gas, volatile substance, or aerosol/particulate).
4 Required if repeated contact with human skin results under conditions of use.
5 Incidents must be reported, if they occur.

Efficacy - Vertebrate Control Agents

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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
INTAGRA, INC.
8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. 4866-9

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1905

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
151B-17(i)	pH (6)					A C IJK	EP	8 mos.	
151B-17(k)	Flammability (7)					A C IJK	EP	8 mos.	
151B-17(l)	Storage stability					A C IJK	EP	8 mos.	
151B-17(m)	Viscosity (8)					A C IJK	EP	8 mos.	
151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
151B-17(o)	Corrosion characteristics					A C IJK	EP	8 mos.	

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

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

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EPA Reg. No. 4866-9

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1905

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
	Acute Toxic - Biochemical								
152B-10	Acute oral toxicity					A C IJK	EP	8 mos.	
152B-11	Acute dermal toxicity					A C IJK	EP	8 mos.	
152B-12	Acute inhalation (3)					A C IJK	EP	8 mos.	
152B-13	Primary eye irritation					A C IJK	EP	8 mos.	
152B-14	Primary dermal irritation					A C IJK	EP	8 mos.	
152B-15	Dermal sensitization (4)					A C IJK	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					A C IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-19	Browsing animal repellents (50)					A C IJK	EP	8 mos.	

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Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

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K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

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8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. 4866-10

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1906

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
151B-17(i)	pH (6)					A C IJK	EP	8 mos.	
151B-17(k)	Flammability (7)					A C IJK	EP	8 mos.	
151B-17(l)	Storage stability					A C IJK	EP	8 mos.	
151B-17(m)	Viscosity (8)					A C IJK	EP	8 mos.	
151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
151B-17(o)	Corrosion characteristics					A C IJK	EP	8 mos.	

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MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids
EPA Reg. No. 4866-10

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1906

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
	Acute Toxic - Biochemical								
152B-10	Acute oral toxicity					A C IJK	EP	8 mos.	
152B-11	Acute dermal toxicity					A C IJK	EP	8 mos.	
152B-12	Acute inhalation (3)					A C IJK	EP	8 mos.	
152B-13	Primary eye irritation					A C IJK	EP	8 mos.	
152B-14	Primary dermal irritation					A C IJK	EP	8 mos.	
152B-15	Dermal sensitization (4)					A C IJK	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					A C IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-19	Browsing animal repellents (50)					A C IJK	EP	8 mos.	

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

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F - Aquatic nonfood industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

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Acute Toxic - Biochemical

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8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. 4866-11

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1907

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
151B-17(i)	pH (6)					A C IJK	EP	8 mos.	
151B-17(k)	Flammability (7)					A C IJK	EP	8 mos.	
151B-17(l)	Storage stability					A C IJK	EP	8 mos.	
151B-17(m)	Viscosity (8)					A C IJK	EP	8 mos.	
151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
151B-17(o)	Corrosion characteristics					A C IJK	EP	8 mos.	

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8500 PILLSBURY AVE. SOUTH
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4079 Putrescent whole egg solids
EPA Reg. No. 4866-11

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 4866-RD-1907

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
	Acute Toxic - Biochemical									
152B-10	Acute oral toxicity					A C	IJK	EP	8 mos.	
152B-11	Acute dermal toxicity					A C	IJK	EP	8 mos.	
152B-12	Acute inhalation (3)					A C	IJK	EP	8 mos.	
152B-13	Primary eye irritation					A C	IJK	EP	8 mos.	
152B-14	Primary dermal irritation					A C	IJK	EP	8 mos.	
152B-15	Dermal sensitization (4)					A C	IJK	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					A C	IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents									
96-19	Browsing animal repellents (50)					A C	IJK	EP	8 mos.	

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Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

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K - Residential outdoor	L - Indoor fpod	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

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Acute Toxic - Biochemical

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Efficacy - Vertebrate Control Agents

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INTAGRA, INC.
8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. OR88001100

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1021-RD-1902

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
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151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
INTAGRA, INC. 8500 PILLSBURY AVE. SOUTH MINNEAPOLIS MN 55420	4079 Putrescent whole egg solids EPA Reg. No. OR88001100	PRODUCT SPECIFIC ID# 1021-RD-1902

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
	Acute Toxic - Biochemical								
152B-10	Acute oral toxicity					A C IJK	EP	8 mos.	
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152B-16	Hypersensitivity incidents (5)					A C IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-19	Browsing animal repellents (50)					A C IJK	EP	8 mos.	

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Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

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8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids

EPA Reg. No. WA88000400

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1021-RD-1903

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
	Prod Chem - Biochemical								
151B-10	Product identity					A C IJK	EP	8 mos.	
151B-11	Manufacturing process					A C IJK	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingredients					A C IJK	EP	8 mos.	
151B-15	Certification of limits					A C IJK	EP	8 mos.	
151B-16	Analytical methods					A C IJK	EP	8 mos.	
151B-17(b)	Physical state					A C IJK	EP	8 mos.	
151B-17(f)	Density					A C IJK	EP	8 mos.	
151B-17(i)	pH (6)					A C IJK	EP	8 mos.	
151B-17(k)	Flammability (7)					A C IJK	EP	8 mos.	
151B-17(l)	Storage stability					A C IJK	EP	8 mos.	
151B-17(m)	Viscosity (8)					A C IJK	EP	8 mos.	
151B-17(n)	Miscibility (9)					A C IJK	EP	8 mos.	
151B-17(o)	Corrosion characteristics								

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
INTAGRA, INC.
8500 PILLSBURY AVE. SOUTH
MINNEAPOLIS MN 55420

2. Case # and Name
4079 Putrescent whole egg solids
EPA Reg. No. WA88000400

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 1021-RD-1903

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
	Acute Toxic - Biochemical								
152B-10	Acute oral toxicity					A C IJK	EP	8 mos.	
152B-11	Acute dermal toxicity					A C IJK	EP	8 mos.	
152B-12	Acute inhalation (3)					A C IJK	EP	8 mos.	
152B-13	Primary eye irritation					A C IJK	EP	8 mos.	
152B-14	Primary dermal irritation					A C IJK	EP	8 mos.	
152B-15	Dermal sensitization (4)					A C IJK	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					A C IJK	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-19	Browsing animal repellents (50)					A C IJK	EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4079 Putrescent whole egg solids

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Biochemical

6 Required if test substance is dispersible with water.
7 Required if product contains combustible liquids.
8 Required if product is a liquid.
9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

3 Required if the product consists of, or under conditions of use results in, an inhalable material (e.g., gas, volatile substance, or aerosol/particulate).
4 Required if repeated contact with human skin results under conditions of use.
5 Incidents must be reported, if they occur.

Efficacy - Vertebrate Control Agents

50 Due to questions concerning the effectiveness of vertebrate animal repellents and the suitability of label directions for such products, registrants of pesticides containing Putrescent Whole Egg Solids must indicate the studies upon which the claims made for their products are based. Such studies in EPA's data base may be cited by MRID number or accession number. Studies not in EPA's data base must be submitted in the appropriate format. If no efficacy data can be provided to substantiate the claims made for their products, registrants must commit to generate such data, delete the relevant claims, or request voluntary cancellation of their registrations.

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

JUL 29 1986

PR NOTICE 86-5

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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****

A. Organization of Submittal Package

A 'submittal package' consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to <u>one</u> study, they should be included as an appendix to that study.

- If such materials relate to <u>more than one</u> study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (ie., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study,

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope: studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed 'example' cite the page number or this notice where the element is illustrated.

Element	When Require	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required.	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies. (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1 Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; DO NOT INCLUDE CBI ON THE TITLE PAGE. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the Statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c). (See Attachment 3) These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(d)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

- The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked 'Confidential Attachment.' An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5 Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (see Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the 'Supplemental Statement of Data Confidentiality Claims'.
- Remove the 'Confidential Attachment'.
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact William C. Grosse, Chief, Information Services Branch, Program Management and Support Division, (703-557-2613).

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1.

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

†Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

†Smith Chemical Corp. will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

.
.
.

Vol n. Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

** Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2.

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3.

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4.

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5.

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1 (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
28	25	"	"
100	19	"	"

Example 2 (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20	4-17	Description of the quality control process	§10(d)(1)(C)

Example 3 (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
39-41	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter _____

Sponsor _____

Study Director _____

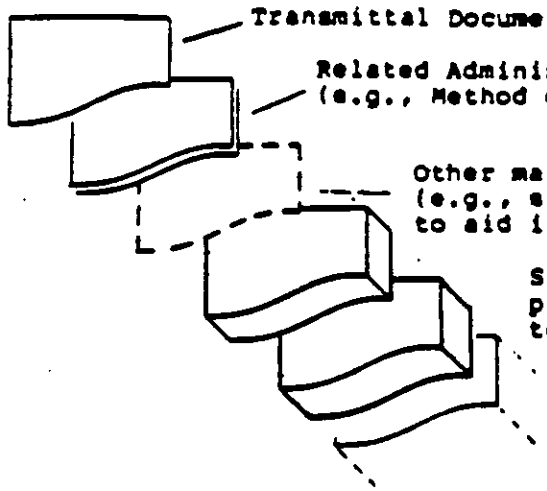
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

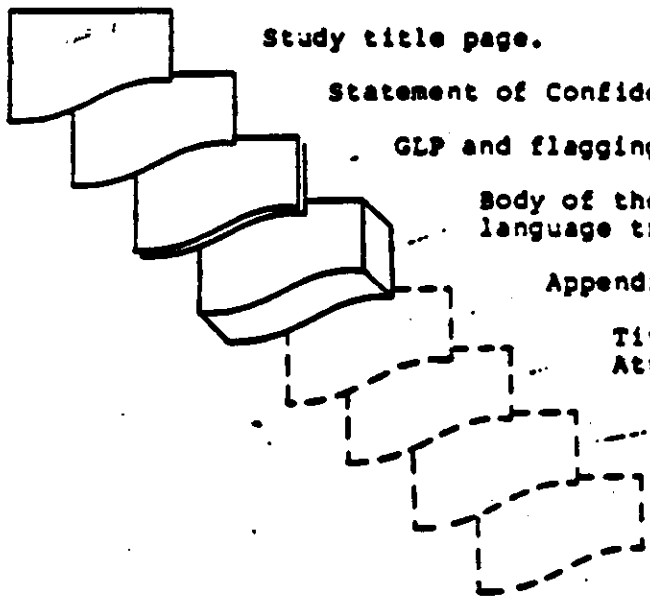
Submitter _____

ATTACHMENT 7.

FORMAT OF THE SUBMITTAL PACKAGE

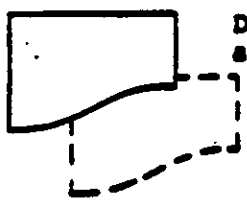


FORMAT OF SUBMITTED STUDIES



* When flagging requirements are finalized.

LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING DATA REQUREMENTS FOR REREGISTRATION

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING PUTRESCENT WHOLE EGG SOLIDS FOR PURPOSES OF 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 putrescent whole egg solids, the Agency considered batching end-use products. This process involves grouping similar products for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.).

However, batching of end-use products containing putrescent whole egg solids was not possible after considering the available information described above. The table below lists all the end-use products containing putrescent whole egg solids. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their products. 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).

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 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). Since the end-use products containing putrescent whole egg solids could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Containing Putrescent Whole Egg Solids

EPA Reg. No.	% Putrescent Whole Egg Solids	Formulation type
4866-8	15.0	Liquid
4866-9	5.0	Liquid
4866-10	37.0	Liquid
4866-11	36.0	Dust

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

151B-10 Product Identity

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Product name and trade name (if different)
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 for certain toxicologically significant impurities (e.g., microbial toxins, 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. ____ Product name, trade name, and common name (if established) for each active ingredient
7. ____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
8. ____ 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
9. ____ Genus and species (and strain, subspecies, isolate, etc., if applicable) from which the biochemical was isolated or with which it is commonly associated
10. ____ Specificity of biochemical activity, the mode of action, and field rates at which the biochemical is active/proposed (units ai/A, etc.)
11. ____ Similarity to the naturally-occurring biochemical, if not derived from a biological entity
12. ____ An updated Confidential Statement of Formula must be provided (EPA Form 8570-4 rev. 9/87).
13. ____ Any known or suspected hazards of the biochemical to man, the environment, or nontarget species.

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

151B-11 Manufacturing Process

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Description of manufacturing process or extraction/isolation steps if obtained from a biological entity.
2. ____ Statement of whether batch or continuous process, if applicable
3. ____ Relative amount of beginning materials and order in which they are added
4. ____ Description of equipment
5. ____ Description of physical conditions (temperature, pH, pressure, humidity) controlled in each step and the parameters that are maintained
6. ____ Statement of whether process involves intended chemical reactions
7. ____ Flow chart with chemical equations for each intended chemical reaction
8. ____ Duration of each step of process
9. ____ Description of purification procedures
10. ____ Description of measures taken to assure quality of final product including identity of the biological source, if applicable
11. ____ A clear presentation of the stage at which inerts are intentionally added, if and when any concentration is effected, the material to be used as the manufacturing use product (MP), whether MP registration is sought, and whether a TGAI/MP is sold and/or shipped.

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

151B-12 Discussion of Formation of Unintended Ingredients

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ 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 present at < 0.1% by weight

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

151B-13 Analysis of Samples

ACCEPTANCE CRITERIA

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 ≥ ≅ 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 should 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. ____ The test material is to be the purest pesticidal grade commercially produced prior to intentional addition of inerts. Generally, this test material is the same as that used for certain nontarget and human hazard testing and is identical to, or equivalent to the technical grade. Any differences from the test substance used for hazard testing should be noted.

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

151B-15 Certification of Limits

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined
2. ____ 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 each limit is determined
3. ____ 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
4. ____ Analytical methods 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.

151B-17 Physical and Chemical Properties

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

A. Color

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

B. 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

C. Odor

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

D. Melting Point

- ___ Reported in °C
- ___ Any observed decomposition reported

E. Boing Point

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

F. Density, Bulk Density, Specific Gravity

- ___ Measured at about 20-25°C
- ___ Density/bulk density reported in g/ml or the specific gravity of liquids reported with reference to water at 20°C [NOTE: For a solid in particulate form a measurement of bulk density may be substituted for measurement of density.]

G. Solubility

- ___ Determined in distilled water, n-octanol 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)

H. Vapor Pressure

- ___ Measured at ≈25°C (or calculated by extrapolation from measurements made at

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

higher temperature if pressure too low to measure at 25°C)
___ Experimental procedure described
___ Reported in mm Hg (torr) or other conventional units

I. pH

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

J. Stability

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

K. Flammability

___ Flash point reported in °F or °C
___ Flame extension or flame projection reported to nearest centimeter or nearest inch

L. Storage Stability

___ Product stored in its commercial package or smaller one of same construction and materials
___ Amount of active ingredient determined in product at beginning and end of test period (duration of at least one year or for a product which degrades sufficient duration to support expiration date)
___ Any deterioration or degradation products determined
___ Product examined for physical changes at end of test
___ Product stored at about 20-25°C (and 50% relative humidity if permeable packaging) or under warehouse conditions reflecting expected storage
___ Report includes duration and conditions of storage, quantitative analyses of active ingredient, and identification of any deterioration, degradation products, or physical changes (and consequences of latter on safe handling and use of product)

M. Viscosity

___ Determined at about 20-25°C
___ Reported in poises, stokes, or other conventional units

N. Miscibility

___ Determined at about 20-25°C
___ Product mixed with petroleum solvents whose composition reflects those on label and at rate on label
___ Mixture examined for separation after 30 minutes

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

O. Corrosion Characteristics

—— Data on corrosion characteristics provided (experimental method described) or reasonable explanation given for lack of corrosiveness based on nature of product (e.g., lack of extreme pH; unreactive)

P. Octanol/water Partition Coefficient

—— Measured at about 20-25°C

—— Experimentally determined and description of procedure pvided (preferred method-45 Fed. Register 77350)

—— Data supporting reported value provided

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

152B-10 Acute Oral Toxicity

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 dose or in fractions over 24 hours.
4.* ____ Vehicle control if other than water.
5. ____ Doses tested, sufficient to determine a toxicity catagy 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.

152B-11 Acute Dermal Toxicity

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 toxicoty catagory 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.

152B-12 Acute Inhalation Toxicity

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. ____ Motor aerodynamic particle size for aerosols.
10. ____ Doses tested, sufficient to determine a toxicity category 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.

152B-13 Primary Eye Irritation

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 ≤ 2 or ≥ 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 ticulate 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 daily observations.

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

152B-14 Primary Dermal Irritation

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 ≤ 2 or ≥ 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.

152B-15 Hypersensitivity

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 ≤ 2 or ≥ 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.

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

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

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 4079 Putrescent whole egg solids

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
004866	INTAGRA, INC.		8500 PILLSBURY AVE. SOUTH	MINNEAPOLIS MN	55420

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
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.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(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).

Signature	Date
Name and 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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

EPA Form 8570-32

US Environmental Protection Agency
Washington, DC 20460

EPA

Product Specific Data Report

Registration Standard for	EPA Registration Number	Form Approved OMB # 2070-005 Expires 11-30-89

Registration Guideline No	Name of Test	Testing not required for my product listed above (Check below)	I am complying with Data Requirements by: Citing MRID No	Submitting Data (Attached) (Check below)	(For EPA Use Only) Accession numbers assigned
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit/rat/g.pig				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements 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.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (H-7508W)
21T-1001x June 1992

EPA R.E.D. FACTS

Putrescent Whole Egg Solids

Pesticide Reregistration

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, showing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for putrescent whole egg solids.

Use Profile

Putrescent whole egg solids are an active ingredient in pesticide products registered for use as animal repellents to protect a variety of trees and shrubs. These products are used in nurseries, large greenhouses and forestry plantations, on a variety of forest, fruit and nut trees, conifers and ornamental woody shrubs. They are applied in dust or liquid form to seedlings or full-grown trees and shrubs to repel black- and white-tailed deer, Roosevelt elk, and mountain beaver.

Regulatory History

EPA registered the first pesticide product containing putrescent whole egg solids as an active ingredient in 1975. Currently, six repellent products containing this active ingredient are registered. In 1985, EPA exempted putrescent whole egg solids from the requirement of a tolerance when used as an animal repellent in or on almonds (see 40 CFR 180.1071). Fresh eggs and egg products are "generally recognized as safe," or GRAS (see 21 CFR 170.3).

Human Health And Environmental Assessment

Although EPA has developed a set of data requirements for reregistration, the Agency believes there is a category of pesticides for which a reduced set of data requirements are appropriate. Such pesticides may be exempt from the usual generic data requirements for toxicology, residue chemistry, human exposure, ecological effects and environmental fate, without compromising human health or environmental safety. However, some data requirements (such as basic product identity and product chemistry data) usually are essential, and generally will not be waived.

Putrescent whole egg solids are in this category of pesticides, and EPA is waiving most of the generic data requirements for their reregistration. Egg solids are a common human food. Putrescent whole egg solids (including inedible egg powder, dried whole egg and powdered inedible egg solids) are produced from eggs that the U.S. Department of Agriculture has declared inedible for human consumption due to cracked shells or imperfections. They are, therefore, a natural product, high in protein, fat, vitamins and minerals.

Used as pesticides, putrescent whole egg solids have a non-toxic mode of action for repelling animals. They are presumed to be non-persistent since they are organic and are known to rapidly degrade in the environment. EPA has received no reports of adverse effects resulting from their use. The Agency believes that no significant adverse effects to humans or the environment are associated with the use of putrescent whole egg solids as pesticides.

Additional Data Required

EPA is not requiring the submission of additional generic data for the active ingredient putrescent whole egg solids. However, EPA is requiring the submission of product specific data (product chemistry, acute toxicity and efficacy). These studies are being required now, through the RED.

Product Labeling Changes Required

The labels of putrescent whole egg solid pesticide products must comply with EPA's current pesticide labeling requirements.

Regulatory Conclusion

- The registered animal repellent uses of putrescent whole egg solids are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.
- The six registered products that contain putrescent whole egg solids as their only active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for putrescent whole egg solids during a 60-day time period, as announced in a Notice of Availability published in the Federal

Register. To obtain a copy of the RED or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the putrescent whole egg solids RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about putrescent whole egg solids or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual putrescent whole egg solids products, please contact the Registration Division, PM-14 (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-6600.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 24 hours a day, seven days a week, or Fax your inquiry to 806-743-3094.