United States Environmental Protection Agency
Office of Pesticide Programs
August 1992

EPA

Reregistration Eligibility Document (RED)

Indole-3-Butyric Acid

REREGISTRATION ELIGIBILITY DOCUMENT

INDOLE-3-BUTYRIC ACID

LIST B

CASE 2330

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

GLOSSARY OF TERMS AND ABBREVIATIONS

CAS	Chemical Abstracts Service
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
MRID	Master Record Identification (number) EPA's system of recording and tracking studies submitted.
RED	Reregistration Eligibility Document

EXECUTIVE SUMMARY

Pesticide products containing indole-3-butyric acid (IBA) as the sole active ingredient, or in combination with other active ingredients, have been registered since October 1960. These products have been registered for use on plant cuttings and transplants of nonfood, ornamental nursery stock to promote root growth and to reduce transplanting shock. In 1990, new products were registered for use on fruit and vegetable crops, field crops and ornamental turf to promote growth development of flowers and fruit and to increase crop yields. Thirty-one products are currently registered with the Environmental Protection Agency ("the Agency").

The Agency has assessed the available scientific information about this compound in relation to all its registered uses to determine its eligibility for reregistration. The data base for IBA is sufficient to allow the Agency to conduct a tentative risk assessment for all uses. Therefore, the Agency has determined that the products containing IBA for all uses are eligible for reregistration.

Before reregistering each product, the Agency is requiring confirmatory acute ecotoxicity data on the active ingredient, product specific data, and revised product labeling to be submitted within eight months from the issuance of this document. 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 IBA, the Agency has batched products which can be considered similar for purposes of acute toxicity. After reviewing these data and revised labels, the Agency will determine whether or not the conditions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 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, the Agency will reregister the products. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

II. CASE OVERVIEW

A. Chemical Overview

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

Common Name: IBA

Chemical Name: Indole-3-Butyric Acid

CAS Registry Number: 133-32-4

Office of Pesticide Programs Chemical Code: 046701

Empirical Formula: $C_{12}\ H_{13}\ NO_2$

Trade and Other Names: Hormodin, Seradix

Basic Manufacturer: Syntex S.A., Chemical Division

B. Use Profile

The following is information on the current registered uses and application methods. A detailed table of all uses of indole-3-butyric acid is in Appendix A.

Type of Pesticide: biochemical pesticide, plant growth regulator

Use Sites: Greenhouse Nonfood - ornamental plants, shade trees and shrubs

Terrestrial Nonfood - ornamental plants, shade trees, shrubs, turf, sod, lawn, golf courses

Residential Indoor/Outdoor - ornamental plants, shade trees and shrubs

Terrestrial Food - fruit, vegetable, field crops

C. Regulatory History

As stated in the Executive Summary, products containing IBA were first registered in October 1960. IBA was originally registered for use on a variety of nonfood ornamental plants, shrubs and shade trees to promote and accelerate root formation of plant clippings and to reduce transplant shock. On October 1990, additional uses were registered for IBA which included fruit and vegetable crops, field crops, and ornamental turf.

On June 28, 1988, the Agency issued a Data Call-In Notice for data on pesticide products containing IBA as the active ingredient. The registrants responded by requesting a low volume minor use data waiver for all applicable guidelines. The Agency was later asked to classify IBA as a biochemical pesticide. Following review, the Agency designated IBA as a biochemical pesticide based on the following scientific reason: 1) IBA is similar in structure and functional identical to a naturally occurring plant hormone or auxin, indole-3-acetic acid.

III. SCIENCE ASSESSMENT OF INDOLE-3-BUTYRIC ACID

A. Product Chemistry Assessment

Indole-3-butyric acid is a synthetic plant hormone which structurally resembles 3-indole acetic acid (IAA), the primary growth hormone, naturally occurring in plants. Several naturally occurring plant hormones have been identified which display structural and physiological activity similar to this compound. Such plant compounds, which are intermediate metabolites produced during the synthesis of 3-indole acetic acid from tryptophan, are thought to be converted to IAA prior to being considered effective when applied to auxin deficient plant tissue.

The molecular weight of IBA is 203.23. IBA is odorless, white or slightly yellow crystals, and has a melting point of 123-125°C. IBA is practically insoluble in water and chloroform but soluble in alcohol, esters and acetone.[2] All generic chemistry data requirements for IBA have been satisfied. Appendix B and C includes references of these data.

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[2] The Merck Index. Eighth Edition p. 565.

3. Human Risk Assessment

As discussed above, the potential risks to humans from occupational exposure to IBA are considered negligible due to: a) the lack of toxicological concerns, b) the low volume/minor use of the product, and c) IBA's structural resemblance to naturally occurring plant hormones.

C. Environmental Assessment

1. Ecological Effects and Environmental Fate Data

Although data from environmental fate and ecological effects studies have not been submitted, the Agency believes that there is sufficient information available to tentatively assess potential environmental risks resulting from the current uses of IBA. Accordingly, the Agency at this time will require environmental effects (ecotoxicity) data only for confirmatory purposes.

The terrestrial crop and turf uses of IBA result in very low exposures to the environment -- the maximum application rate is 7 mg/acre/crop season (1.7×10^{-5} pounds/acre). By comparison, this rate is five orders of magnitude lower than use rates typical of conventional pesticides and lower than most other biochemicals. Low application rates of IBA to crop land result in correspondingly low environmental concentrations and exposure to nontarget plants and animals. The Agency recognizes that IBA's low application rate alone is not sufficient evidence on which to base an environmental assessment. However, IBA's low application rate combined with its similarity in structure and physiological function to natural plant growth regulators are important factors to consider when assessing potential risks to nontarget terrestrial and aquatic plants and animals.

Indole-3-butyric acid (IBA) is similar in structure and biological activity to the naturally occurring plant growth hormone indole-3-acetic acid (IAA), a principal hormone of higher plants. Compounds similar to IBA (indoleacetamide, indoleacetaldehyde, indoleacetonitrile, and indolepyruvic acid) are intermediate metabolites in the synthesis of IAA from the amino acid tryptophan, which occurs widely in plants, fungi, bacteria, humans and other species. In fact, the average human excretes approximately 7 mg of IAA in urine daily. Given this occurrence of tryptophan and IAA in such a wide diversity of organisms, it is reasonable to assume IAA and similar compounds have metabolic pathways in avian and aquatic species.

Even though specific data have not been submitted, the Agency believes that IBA applied to the environment may be metabolized to IAA and other metabolites by soil, plant, and aquatic microorganisms. The chemical structure of IBA is very similar to IAA, the difference being that the aliphatic side chain contains two additional carbon

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR INDOLE-3-BUTYRIC ACID

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA requires the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has waived the submission of most generic (i.e., active ingredient specific) data, except for technical chemistry data and acute ecotoxicity data for confirmatory reasons. The Agency has completed its review of the technical chemistry data and other factors and considerations, and has determined that this information is sufficient to support reregistration of all products containing IBA for all uses. Appendix B identifies the generic studies that the Agency reviewed for the determination of reregistration eligibility for IBA.

The Agency therefore finds that products containing only IBA as an active ingredient are eligible for reregistration once the product specific data, confirmatory ecotoxicity data, and amended labeling are received and accepted by the Agency. Products that contain additional active ingredients will be reregistered once the Agency completes eligibility decisions on the other active ingredients and once product specific and amended labeling are received and accepted. The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

Although the Agency has found that all products containing IBA are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action and/or require the submission of additional data to support reregistration of products containing IBA, if new information comes to the Agency's attention or if the data requirements for registration change.

V. ACTIONS REQUIRED BY REGISTRANTS

A. Determination of Eligibility

Based on consideration of data and information submitted for the active ingredient, IBA and the registered use patterns, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA requires that the Agency obtain any needed product-specific data regarding the pesticide following a determination of eligibility. The Agency will review these data and the confirmatory ecotoxicity data and determine whether to reregister individual products.

APPENDIX A

Indole-3-butyric Acid Use Patterns Subject to Reregistration

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]									
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Apps	Max. # Apps @ Max. Rate (Days)	Minimum Interval Between Apps. @ Max (Days)	Restricted Interval (Days)	Geographic Limitations	Use Limitation (code)
Dust, Root stock, Dust bag	D	na	Not specified	Not spec	Not spec	Not spec	None	None	
Dust, Seed, Dust bag	D	na	Not specified	Not spec	Not spec	Not spec	None	None	
Soil drench, Post planting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	7	None	None	
ORNAMENTAL HERBACEOUS PLANTSUse Group(s):Terrestrial Non-Food Crop, Greenhouse Non-Food Crop, Indoor Residential and Outdoor Residential									
Soil drench, Transplant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	7	None	None	
Soil treatment, At planting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Postplant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Pretransplant, Not on label	D	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Pretransplant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Not on label, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spot soil treatment, Plant bed, Not on label	D	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spot soil treatment, Plant bed, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spot soil treatment, Post planting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Apps	Max. # Apps @ Max. Rate (Days)	Minimum Interval Between Apps. @ Max (Days)	Restricted Interval (Days)	Geographic Limitations	Use Limitation (code)
ORNAMENTAL WOODY SHRUBS AND VINES Use Group(s): Terrestrial Non-Food Crop, Greenhouse Non-Food Crop and Outdoor Residential									
Chemigation, Foliar, Irrigation	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Dip, Cutting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Dip, Cutting, Not on label	WP/D	na	Not specified	Not spec	Not spec	Not spec	None	None	
Dust, Cutting, Hand held duster	D	na	Not specified	Not spec	Not spec	Not spec	None	None	
Dust, Cutting, Not on label	D	na	0.001 ai lb/35,000 cuttings	Not spec	Not spec	Not spec	None	None	
Soil treatment, At planting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Post planting, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Soil treatment, Pretransplant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spot soil treatment, Post plant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spot soil treatment, Preplant, Not on label	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]									
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Apps	Max. # Apps @ Max. Rate (Days)	Minimum Interval Between Apps. @ Max (Days)	Restricted Interval (Days)	Geographic Limitations	Use Limitation (code)
ORNAMENTAL AND/OR SHADE TREESUse Group(s):Terrestrial Non-Food Crop, Greenhouse Non-Food Crop and Outdoor Residential									
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	Not spec	Not spec	Not spec	None	None	
FOOD/FEED USES - **ELIGIBLE FOR REREGISTRATION**									
BARLEY (CEREAL GRAIN) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	

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BROCCOLI Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Post transplant, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Post transplant, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	

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CABBAGE Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Post transplant, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	
Broadcast, Post transplant, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	14	None	None	

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SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max # Apps	Max. # Apps @ Max. Rate (Days)	Minimum Interval Between Apps. @ Max (Days)	Restricted Interval (Days)	Geographic Limitations	Use Limitation (code)
CITRUS FRUITS Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Dip, Transplants, Not on label	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Directed spray, Transplants, Not on label	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Spray, Foliar, Not on label	SC/L	na	not specified	3/year	Not spec	Not spec	None	None	
CORN, FIELD,SWEET (CEREAL GRAIN) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Premergence, Ground	SC/L	na	0.0000078 lb ai/A	1	1	na	None	None	
Broadcast, Premergence, Aircraft	SC/L	na	0.0000078 lb ai/A	1	1	Not spec	None	None	
Band, Foliar, Ground	SC/L	na	0.0000026 lb ai/A	1	1	Not spec	None	None	

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CUCUMBER Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000024 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000024 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000024 lb ai/A	Not spec	Not spec	7	None	None	

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MELONS Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000029 lb ai/A	2	2	14	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000029 lb ai/A	2	2	14	None	None	
MUSTARD CABBAGE (PAKSHOI) Use Group(s): Terrestrial Food Crop									
Band, Foliar, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Cutting, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Cutting, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]

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OATS (CEREAL GRAIN) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
ONION Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	not specified	Not spec	Not spec	Not spec	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	not specified	Not spec	Not spec	Not spec	Not Spec	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]

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PEAS Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Broadcast, Foliar, Aircraft	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	7	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	7	Not Spec	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
PEPPER Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	7	None	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]

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RICE Use Group(s): Terrestrial Food Crop, Terrestrial Feed Crop and Aquatic Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000078 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000078 lb ai/A	Not spec	Not spec	Not spec	None	None	
RYE (CEREAL GRAIN) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	

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SOYBEANS (UNSPECIFIED) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Preplant incorporated, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	

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SQUASH (SUMMER/WINTER/ ZUCCHINI) Use Group(s): Terrestrial Food Crop									
Broadcast, Foliar, Aircraft	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	7	None	None	
STRAWBERRY Use Group(s): Terrestrial Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000029 lb ai/A	Not spec	Not spec	Not spec	None	None	

APPENDIX A:Case 2330 [Indole-3-butyric acid] Chemical 046701 [Indole-3-butyric acid]

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TOMATO Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Band, Post transplant, Ground	SC/L	na	0.0000013 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Aircraft	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Post transplant, Aircraft	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Bloom, Ground	SC/L	na	0.0000059 lb ai/A	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Ground	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	7	None	None	
Broadcast, Post transplant, Ground	SC/L	na	0.000002 lb ai/A	Not spec	Not spec	Not spec	None	None	

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WHEAT (CEREAL GRAIN) Use Group(s): Terrestrial Food Crop and Terrestrial Feed Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Aircraft	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
Broadcast, Foliar, Ground	SC/L	na	0.0000053 lb ai/A	Not spec	Not spec	Not spec	Not Spec	None	
NON-FOOD/NON-FEED USES - ELIGIBLE FOR REREGISTRATION									
GOLF COURSE TURF Use Group(s): Terrestrial Non-Food Crop									
Chemigation, Foliar, Irrigation	SC/L	na	not specified	Not spec	Not spec	Not spec	None	None	
Broadcast, Foliar, Ground	SC/L	na	.000017 lb ai/A	Not spec	Not spec	30	none	none	

APPENDIX B

Generic Data Requirements for Reregistration of Indole 3-Butyric Acid and Data Citations Supporting Reregistration

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Indole-3-Butyric Acid

Guideline Citation	Title of study	Use Pattern	Citation
§158.690 Product Chemistry			
151-10	Product Identity	CIKO	41584401
151-11	Manufacturing Process	CIKO	41584401
151-12	Discussion of Formation	CIKO	41584401
151-13	Analysis of samples	CIKO	41584402
151-15	Certification of limits	CIKO	41584402
151-16	Analytical Method	CIKO	41584402
151-17(a)	Color	CIKO	41584403
151-17(b)	Physical State	CIKO	41584403
151-17(c)	Odor	CIKO	41584403

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Indole-3-Butyric Acid

Guideline Citation	Title of Study	Use Pattern	Citation
§158.690 Toxicology			
152-11	Acute Oral	CIKO	Waived
152-11	Acute dermal	CIKO	Waived
152-12	Acute inhalation	CIKO	Waived
152-21	90-day dermal	CIKO	Waived
152-23	Teratogenicity	CIKO	Waived
152-19	Mutagenicity	CIKO	Waived

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 Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3.

IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier number, or "MRID". 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 also is to be used whenever specific reference is needed.

4.

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

a. –.

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

b.

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

c.

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

d.

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

APPENDIX C

INDOLE-3-BUTYRIC ACID BIBLIOGRAPHY

MRID Citation

41193801 Syntex Corp. (1989) Indole-3-butyric Acid: Product Identity and Composition. Unpublished study. 56 p.

41584401 Syntex Corp. (1990) Addendum to Guideline 61... per EPA request 1/29/90: Indole-3-Butyric Acid, Product Identity and Composition. 17p.

41193701 Syntex Corp. (1989) Indole-3-Butyric Acid: Analysis and Certification of Product Ingredients. Unpublished study. 20 p.

41584402 Syntex Corp. (1990) Addendum to Guideline 62... per EPA request of 1/29/90: Indole-3-Butyric Acid, Analysis and of Product Ingredients: 20 p.

41193702 Syntex Corp. (1989) Indole-3-butyric Acid: Physical and Chemical Characteristics. Unpublished study. 3 p.

41584403 Syntex Corp. (1990) Addendum to Guideline 63 ...per EPA request of 1/29/90: Indole-3-butyric Acid: Physical and Chemical Characteristics. 55 p.

EPA'S BATCHING OF INDOLE-3-BUTYRIC ACID END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient indole-3-butyric acid, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table II lists 14 products that were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table II.

EPA Reg. No.	% Indole-3-butyric acid (IBA) & Other Active Ingredients	Formulation Type
572-334	18.3 IBA 20.0 Thiram	Powder
869-60	0.0004 IBA	Powder
5332-10	0.1 IBA	Powder
7401-252	0.0004 IBA	Emulsifiable Conc.
8281-7	0.013 IBA 0.240 Naphthalene acetic acid	Liquid
9779-313	0.0000625 IBA 0.0000625 Gibberellic acid	Liquid
9779-321	0.0015 IBA 0.0015 Gibberellic acid	Liquid
10370-184	0.003 IBA	Emulsifiable Conc.
42473-1	97.0 IBA	Liquid
43905-1	1.0 IBA 0.51 Napthelene acetic acid	Liquid
56644-49	0.1 IBA	Liquid
56644-61	0.003 IBA	Liquid
63079-1	0.001 IBA 0.001 Gibberellic acid	Liquid
64388-1	1.0 IBA 0.5 Naphthalene acetic acid	Liquid

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-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-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.

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.

154B-6 Acute Avian Oral Test

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

TIER I

1. ____ Raw data in support of final report are available
2. ____ Chemical name of test substance
3. ____ Technical grade active ingredient (TGAI) used in test
4. ____ Percent active ingredient
5. ____ Name and percent of related compounds and impurities
6. ____ The pesticide dose as recommended in Subdivision M
7. ____ Test bird used was mallard duck or bobwhite quail
8. ____ Number of birds/treatment level(s) and controls (10 each)
9. ____ Type of controls listed, including solvent, carrier, or whether negative or positive
10. ____ Diet and any antibiotics, vitamins or food additives described
11. ____ Observation period (>14 days)

Result reporting:

12. ____ Include LD_{50} value in mg/kg and the no-observed-effect level
13. ____ Raw mortality data provided
14. ____ Description of observed toxic effects, including death and any other abnormal signs or behavior
15. ____ Pathological changes as noted by gross necropsy examination described

16. ____ Rationale for deviations from the protocol and the effect, if any, these deviations had on the outcome of the study

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

154B-8 Freshwater Fish LC_{50} Test

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Raw data in support of final report are available
2. ____ Chemical name of test substance
3. ____ Technical grade active ingredient (TGAI) used in test
4. ____ Percent active ingredient
5. ____ Name and percent of related compounds and impurities
6. ____ Test fish used was rainbow trout
7. ____ Number of fish/treatment level(s) and controls (10 each)
8. ____ 5 treatment groups used
9. ____ The pesticide dose as recommended in Subdivision M
10. ____ Type of controls listed, including solvent, carrier, or whether negative or positive
11. ____ Observation period (minimum 96 hours)

Result reporting:

12. ____ LC_{50} and/or EC_{50} value and the no-observed-effect level reported in ppm
13. ____ Raw mortality data provided
14. ____ Description of observed toxic effects, including death and any other abnormal signs or behavior
15. ____ Pathological changes as noted by gross necropsy examination described
16. ____ Rationale for deviations from the protocol and the effect, if any, these deviations had on the outcome of the study

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

154B-10 Nontarget Plant Studies (Seed Germination/Seedling Emergence)

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Raw data in support of final report are available
2. ____ Chemical name of test substance
3. ____ Technical grade active ingredient (TGAI) used in test
4. ____ Percent active ingredient
5. ____ Name and percent of related compounds and impurities
6. ____ Plants tested were six dictyledoneae species from at least four families and four monocotyledoneae species from at least two families (corn, soybean, and a root crop must be included)
7. ____ Dose rates in ppm and lb ai/a at the maximum label rate
8. ____ ≥10 seeds planted/container
9. ____ ≥3 treatment groups used
10. ____ Type of controls listed, including solvent, carrier, or whether negative or positive
11. ____ Test duration and observation periods were 5 days for seed germination and two weeks for seedling emergence

Result reporting:

12. ____ Percent germination and percent emergence recorded
13. ____ Description of observed phytotoxic effects
14. ____ Rationale for deviations from the protocol and the effect, if any, these deviations had on the outcome of the study

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

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

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

EPA Form 8570-32