COMPOSITE
GUIDANCE PACKAGE
FOR SIX REGISTRATION STANDARDS

This package represents the "boiler-plate" guidance for preparation of pesticide reregistration submissions, plus detailed information pertaining to each of the following active ingredients listed below:

Active Ingredient	Product Manager
0,0,0,0-Tetrapropyl Dithiopyrophosphate (Aspon®)	William Miller 426-9458
4-Aminopyridine (Avitrol®)	William Miller 426-9458
1,4-Dichloro-2,5 Dimethoxybenzene (Chloroneb)	Henry Jacoby 755-2562
2-Chloro-N(2-ethyl-6-methylphenyl) -N-(2-methoxy-1-methylethyl) (Metolachlor)	Richard Mountfort 755-1397
5-Ethoxy-3-trichloromethyl -1,2,4-thiadiazole (Terrazole®)	Henry Jacoby 755-2562
3-(alpha-acetonylfurfuryl) -4-hydroxycoumarin) Fumarin® and its Sodium Salt	William Miller 426-9458

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

26047

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Certified Mail

Registrant's Address

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing _____ as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (FIFRA), the Office of Pesticide Programs, EPA, has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975 and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) was registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently, submit revised product labeling and associated information.

This mailing contains the Registration Standard, a Guidance Package for preparation of submissions, as well as a listing of your affected products (Attachment A) and a separate list of registrants with products containing this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development. Together they should provide you with all the information you need to meet the necessary requirements and to allow you to continue your registration(s) in effect.

The Registration Standard sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, EPA's assessment of the hazards associated with uses of the pesticide, as best they can be assessed with the data currently available, and its rationale for the regulatory actions being taken at this time.

The Guidance Package, together with the first and second chapters of the Standard contain instructions describing what you must do to bring your product(s) into compliance with the Registration Standard. Products not brought into compliance with the Registration Standard will be subject to suspension and/or cancellation.

Specifically, the enclosed guidance package does the following:

1. Introduces the purpose for the guidance package.

2. Explains data compensation.

3. Explains the Agency's policy regarding data submission and identifies the data, both generic and product specific in three tables, that must be submitted to complete the Agency's evaluation of each product.

4. Sets out time frames for submission of labeling, submission of required data, and compliance with classification and packaging requirements.

5. Explains how to revise labeling in accordance with the Standard and provides classification and package instructions.

6. Provides submission instructions.

Additionally, we suggest that you review the first chapter of the Registration Standard prior to reading the guidance Package, since that chapter describes the Registration background and Standard concept. Because of the variety and complexity of the requirements, and the short statutory time frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that if you do not respond, or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do, or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way.

(202) _____
Registration Division TS-767
Office of Pesticide Programs
Environmental Protection Agency
Washington, D. C. 20460

Douglas D. Campt
Director
Registration Division (TS-767)

Attachment A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Attachment B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company's address, active ingredient, percentage of active ingrident and type of formulation such as Manufacturing Use Product (MUP), Technical Product (TP), wettable powder (WP), and emulsifiable concentrate (EC).

GUIDANCE PACKAGE FOR

REREGISTRATION OF PESTICIDE PRODUCTS

IN COMPLIANCE WITH

REGISTRATION STANDARD

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION DIVISION

WASHINGTON, D.C.

SEPTEMBER 30, 1980

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APPENDICES

I. INTRODUCTION

This guidance package has been prepared to provide you, the registrant, with specific information with which you may maintain in effect your current registration(s) that is subject to this Registration Standard. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirement in this standard, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this package, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following package within the time frames outlined.

II. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix II-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D)

B. A statement acknowledging that if EPA approves your application for reregistration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing Use and End Use Products" (Table A at the end of Section III), is relevant to EPA's evaluation of the registrability of your product (taking into account your product's composition and formulation category, and the uses of your product which its label will permit).

2. The "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix II-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who, according to the Standard, was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:

a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

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*/ For an explanation of the terms "generic" data and "product-specific" data, see pp. 3-4 of the Registration Standard.

b. FIFRA Section 3(c)(2)(D) provides that you need not furnish an offer with respect to any "generic" data, if your product is an end-use product and if its active ingredient will be present in your product solely because of the incorporation into your product of another registered manufacturing-use product which contains that active ingredient and which you purchase from another producer. Note: This exemption does not cover "product-specific" data.

c. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). Of the various persons who submitted data listed in the Standard's bibliography as supporting the Standard, only the following firms have not waived their rights to receive offers:

COMPANIES THAT MAY NEED TO RECEIVE
OFFERS TO PAY FOR § 3(C)(1)(D)

Aspon[R]

Chevron Chemical Company
Ortho Division
940 Hensley Street
Richmond, California 94804

Stauffer Chemical Company
Labeling and Registration Department
1200 South 47th Street
Richmond, California 94804

Avitrol[R]

Avitrol Corporation
7644 E. 46th Street
P.O. Box 45141
Tulsa, Oklahoma 74145

Chloroneb

E. I. duPont de Nemours Company
Legal Department
Wilmington, Delaware 19898

O. M. Scott & Sons Company
Marysville, Ohio 43040

Metolachlor

Ciba-Geigy Corporation
410 Swing Road
Greensboro, North Carolina 27409

Terrazole[R]

Olin Corporation
120 Long Ridge Road
Stamford, Connecticut 06904

Mallinckrodt, Incorporated
Second and Mallinckrodt Streets
St. Louis, Missouri 63147

COMPANIES THAT MAY NEED TO RECEIVE OFFERS
TO PAY FOR § 3(C)(1)(D) (cont'd)

Fumarin[R]

Amchem Products Incorporated
Brookside Avenue
Ambler, PA 19002

d. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

e. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

a. A notification of your intent to apply for reregistration under the Standard, and the name, active ingredient, and intended uses of your product.

b. An offer to pay the person compensation, with respect to approval of your application, to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

c. Your name, mailing address, and telephone number.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the Guidance Package is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this Guidance Package. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. Entitlement of Certain End-Use Registrants to An Exemption. Under the circumstances described in this section III(B), EPA will refrain from suspending the registration of an end-use product even if its registrant does not submit data in response to this Notice. EPA's position is based on the intent of Congress as set forth in FIFRA Section 3(c)(2)(D). Under that section, if generic data on an active ingredient had already been submitted to EPA, an applicant for registration of an end-use product would be excused from the normal Section 3(c)(1)(D) requirement of submitting or citing, and offering to pay compensation for, those data as a condition of obtaining registration. To qualify for that exemption, the active ingredient must be present in his product solely as a result of his incorporation into his product (during formulation or packaging) of a manufacturing-use product containing that active ingredient registered under FIFRA and purchased from another producer. The object of this provision is to simplify data compensation by making compensation for the generic data on the active ingredient an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the active ingredient in his product is being purchased from a firm which is required to submit (or to offer to share in the cost of obtaining) the generic data required by this Notice.

If a registrant who is subject to this Section 3(c)(2)(B) Notice fails to comply with the data submission requirement, the Administrator may suspend his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if

1. the registration is for an end-use product, as opposed to a manufacturing-use product; and

2. the active ingredient in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, is registered under FIFRA, and is purchased by the registrant; and

3. the registrant completes and executes a "Generic Data Exemption Statement" (Appendix III-1) for the end-use products, and submits it to EPA within 90 days of receipt of this Notice; and

4. one or more registrants actually does undertake to submit, and does submit, all the data required by this Notice.

C. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products to which the Standard applies, and the dates by which the data must be submitted . The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The Pesticide Registration Guidelines, */ or data collected under the approved protocols of the Organization for Economic Cooperation Development (OECD) which are yet to be published. If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may delete those uses at the time you submit your revised labeling for registration.

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*/ The Pesticide Registration Guidelines were proposed in two separate publications. On July 1, 1978 EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic-data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data which are required on each formulation, regardless of type of formulation. Product-specific data are further explained under Section IV of this document and are specified in Tables B and C at the end of this Section.

D. Options Available For Complying With Requirements to Submit Data.

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" (Appendix III-2) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. Attach a completed "Generic Data Exemption Statement" (Appendix III-1).

2. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

3. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must at the same time notify EPA which registrant(s) are parties to the agreement. At least one of the parties to the agreement must respond to this Notice in the manner specified by paragraph III (D)(1) above.

4. File with EPA a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants for Development of Data" (Appendix III-3) */.

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)] and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

5. Request that EPA amend your registration by deleting the uses for which the data are needed.

6. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

E. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE

(ASPON^{R})

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

TABLE A

GUIDELINES CITATION	NAME OF TEST	USE PATTERN	MUST APPLICANT ACKNOWLEDGE RELIANCE UNDER FIFRA §3(c)(1)(D)	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER FIFRA §3(c)(2)(B)	MONTHS ALLOWED BEFORE SUB-MISSION
63.62-7(b)	Hydrolysis	Non-Domestic/Domestic, Outdoor, Non-food	No		Yes	24
-7(c)	Photodegradation	"	"		"	24
63.62-8(b)	Aerobic soil metabolism	"	"		"	24
63.62-8(f)(2)	Effects of microbes on pesticide	"	"		"	24
-8(f)(3)	Effects of pesticides on microbe	"	"		"	24
-8(g)	Activated sludge metabolism	"	"		"	24
63.62-9(b)	Leaching	"	"		"	24
-9(d)	Adsorption/desorption	"	"		"	24
63.62-10(b)	Terrestrial field dissipation*	"	"		"	24
63.62-11(d)	Fish accumulation	"	"		"	24
Test on Typical formulated Product						

O,O,O,O- TETRAPROPYL DITHIOPYROPHOSPHATE (ASPON^{R})

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

TABLE A Cont'd.

GUIDELINES CITATION	NAME OF TEST	USE PATTERN	MUST APPLICANT ACKNOWLEDGE RELIANCE UNDER FIFRA §3(c)(1)(D)	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER FIFRA §3(c)(2)(B)	MONTHS ALLOWED BEFORE SUB-MISSION
163.81-1	Acute oral toxicity*	Non-domestic/Domestic, Outdoor, Non-food	No		Yes	6
-2	Acute dermal toxicity*	"	"		"	6
-3	Acute inhalation toxicity	"	"		"	6
-7	Acute delayed neurotoxicity	"	"		"	24
163.83-3	Teratogenicity	"	"		"	24
163.71-1	Avian single-dose LD_{50}*	"	"		"	6
163.72-3	Acute toxicity to estuarine and marine organisms*	"	"		"	6

*Required on Technical Product

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Table B

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.61-3	Product Identity and disclosure of Ingredients	Any percentage active ingredient	No		Yes	6
-4	Description of manufacturing process	"	"		"	24
-5	Discussion on formation of unintentional ingredients	"	"		"	24
-6	Declaration and certification of ingredient limits	"	"		"	6(24mos.*)
-7	Product analytical methods and data	"	"		"	6
163.61-8(1)	Color (Technical)	"	"		"	6
-8(2)	Odor (Technical)	"	"		"	6
-8(3)	Melting Point (Technical)	"	"		"	6
-8(4)	Solubility (Technical)	"	"		"	6
-8(5)	Stability (Technical)	"	"		"	6
-8(6)	Octanol/water partition coefficient (Technical)	"	"		"	6
-8(7)	Physical State (Manufacturing-use Product and the Technical)	"	"		"	6

* Any impurities at 0.1% or less-Information need not be submitted until 24 mos.

O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE (ASPON^{R})

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Table B Cont'd.

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
-8(8)	Density or specific gravity (Manufacturing-use Product and the Technical)	Any percentage active ingredient	No		Yes	6
-8(9)	Boiling Point (Manufacturing-use Product and the Technical)	"	"		"	6
-8(10)	Vapor pressure (Manufacturing-use Product and the Technical)	"	"		"	6
-8(11)	p^H (Manufacturing-use Product and the Technical)	"	"		"	6
-8(12)	Storage Stability	"	"		"	6
-8(13)	Flammability	"	"		"	6
-8(14)	Oxidizing or reducing action	"	"		"	6
-8(15)	Explosiveness	"	"		"	6
-8(17)	Viscosity	"	"		"	6
-8(18)	Corrosion characteristics	"	"		"	6

O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE (ASPON^R)

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Table B Cont'd.

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.81-1	Acute oral toxicity	Any percentage active ingredient	No		Yes	6
-2	Acute dermal toxicity	"	"		"	6
-3	Acute inhalation toxicity	"	"		"	6
-4	Primary eye irritation	"	"		"	6
-5	Primary dermal irritation	"	"		"	6
-6	Dermal sensitization	"	"		"	6

O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE (ASPON^{R})

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Table C

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.61-3	Product identity and disclosure of ingredients	All EC Products	No		Yes	6
		Granular Products	"		"	6
-4	Description of manufacturing process	All EC Products	"		"	24
		Granular Products	"		"	24
-5	Discussion on formation of unintentional ingredients	All EC Products	"		"	6 (24mos*)
		Granular Products	"		"	6 (24mos*)
-6	Declaration and certification of ingredient limits	All EC Products	"		"	6
		Grandular Products	"		"	6
-7	Product analytical methods and data	All EC Products	"		"	6
		Granular Products	"		"	6
163.61-8(1)	Color **	All EC Products	"		"	6
		Granular Products	"		"	6
-8(2)	Odor **	All EC Products	"		"	6
		Gran ular Products	"		"	6
-8(8)	Density or specific gravity **	All EC Products	"		"	6
		Gran ular Products	"		"	6
-8(12)	Storage Stability	All EC Products	"		"	6
		Granular Products	"		"	6
-8(13)	Flammability	All EC Products	"		"	6
-8(14)	Oxidizing or reducing action	All EC Products	"		"	6
		Granular Products	"		"	6
-8(15)	Explosiveness	All EC Products	"		"	6
		Granular Products	"		"	6
-8(16)	Miscibility	All EC Products	"		"	6

* Any impurities at 0.1% or less-Information need not be submitted until 24 mos.
** Required on both the formulated and the technical product.

O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE (ASPON^{R})

Table C Cont'd.

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Guidelines Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Months Allowed Before Submission
-8(17)	Viscosity	All EC Products	No		Yes	6
-8(18)	Corrosion characteristics	All EC Products	"		"	6
		Granular Products	"		"	6
-8(19)	Dielectric breakdown voltage	All EC Products	"		"	6

Table 2. Cont'd.

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.81-1	Acute Oral Toxicity ***	EC's between 12% and 28% a.i.	No		Yes	6
		EC's between 65% and 68% a.i.	No		Yes	6
		EC's with Aspon and other active ingredients	No		Yes	6
		Granulars between 1% and 6%	Yes	000004857	No	6
163.81-2	Acute Dermal Toxicity ***	EC's between 12% and 28% a.i.	Yes	000004838	No	6
		EC's between 65% and 68% a.i.	No		Yes	6
		EC's with Aspon and other active ingredients	No		Yes	6
		Granulars between 1% and 6%	Yes	000004858	No	6
163.81-3	Acute Inhalation Toxicity ***	EC's between 12% and 28% a.i.	No		Yes	6
		EC's between 65% and 68% a.i.	No		Yes	6
		EC's with Aspon and other active ingredients	No		Yes	6
		Granulars between 1% and 6%	No		Yes	6
163.81-4	Primary Eye Irritation ***	EC's between 12% and 28% a.i.	Yes	000004833 or 000004836 or 000004835	No	6
		EC's between 65% and 68% a.i.	No		Yes	6
		EC's with Aspon and other active ingredients	No		Yes	6
		Granulars between 1% and 6%	Yes	000004861	No	6
163.81-5	Primary Dermal Irritation ***	EC's between 12% and 28% a.i.	Yes	000004837	No	6
		EC's between 65% and 68% a.i.	No		Yes	6
		EC's with Aspon and other active ingredients	No		Yes	6
		Granulars between 1% and 6%	Yes	000004859	No	6

*** Test on formulated product as described on pg. 20 of the Registration Standard.

4-aminopyridine

(Avitrol^{R})

Table A GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY F.I.F.R.A. Section 3(c)(2)(D).

GUIDELINES SECTION	NAME OF TEST	USE PATTERN OR COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)*	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
	Environmental Chemistry					
163.62-8(b)	Aerobic Soil Metabolism	All	Yes	05003185	No	
163.62-9	Leaching	All	Yes	05003185 00004001	No	
	Ecological Effects					
163.71-1	Avian Single-Dose LD_{50}	All	Yes	05003186 05003101	No	
163.71-2	Avian Dietary LC_{50}	All	Yes	05003186 00003998 00004083 05003191 GS-0015-004	No	
163.71-4	Avian Reproduction	All	Yes	05003186	No	
163.72-1	Fish Acute LC_{50}	All	Yes	00004083	No	
163.71-5(1)	Cage or Pen Field Test	All	Yes	00003999 00004101 00004083	No	

*All citations must be listed where data must be acknowledged.

Table A (Continued)

GUIDELINES SECTION	NAME OF TEST	USE PATTERN OR COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)*	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
163.71-5(2)	Full Scale Field	All Formulations	Yes	00004079	No	24
Special Test Requirement (See 163.70-1)	Secondary Poisoning	All Formulations	Yes	00003965	No	24
	Toxicology					
163.81-1	Acute Oral Toxicity	All	Yes	00004024	No	
163.81-2	Acute Dermal Toxicity	All	Yes	00004024	No	
163.82-1	Subchronic Oral Toxicity	All	Yes	00004026 00004027	No	
163.82-4	Subchronic Inhalation Requirements	Dusts without Protective Clothing Requirements	No		Yes	24
		All Other Formulations	No		No	
163.83-3	Teratogenicity	Dusts without Protective Clothing Requirements	No		Yes	24
		All Other Formulations	No		No	

*All citations must be listed where data must be acknowledged.

Table A (Continued)

GUIDELINES SECTION	NAME OF TEST	USE PATTERN OR COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)*	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
163.83-1,2,3,4	Mutagencity	Dusts without Protective Clothing Requirements	No		No	24
		All Other Formulations	No		No	
	Residue Chemistry					
None	Plant Metabolism	Non-Crop	No		No	
		Corn	Yes	05003202 00004039	No	
		Sunflowers	Yes	00004088	No	
None	Analytical Method for Determining Residues in Crops	Corn and Sunflowers	Yes	05003193 00004030 00004016 00004007 00004126 00004011 00004029	No	
		Sunflowers (only)	Yes	00004050 00004048 05003192	No	
		Non-Crop	No		No	

*All citations must be listed where data must be acknowledged.

Table A (Continued)

GUIDELINES SECTION	NAME OF TEST	USE PATTERN OR COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)*	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
None	Residue Chemistry (Continued) Residue Data	Corn	Yes	00003993 00004017 00004022	No	
		Sunflowers	Yes	00004089	No	
		Non-Crop	No		No	

*All citations must be listed where data must be acknowledged.

Table B PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation(s)	Must Date Be Submitted Under FIFRA §3(c)(2)(B)?	Months Allowed Before Submission
	Product Chemistry					
163.61-3	Product Identity and Disclosure of Ingredients	Technical and other Manufacturing Use Formulations	No	05010341 05006181 (Active ingredient only)	Yes	6
163.61-4	Description of Manufacturing Processes	Technical and other Manufacturing Use Formulations	No		Yes	24
163.61-5	Formation of Ingredients	Technical and other Manufacturing Use Formulations	No		Yes	24
163.61-6	Certification of Ingredient Limits	Technical and other Manufacturing Use Formulations	No		Yes	6 (24)*
163.61-7	Product Analytical Methods Data	Technical	No		Yes	6
		Other Manufacturing Use Formulations	Yes	00004112	No	6

*24 months permitted for submission of information on impurities present as less than 0.1% of total product. Information on impurities present at greater concentrations will be submitted within 6 months.

Table B (Continued)

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation(s)	Must Date Be Submitted Under FIFRA §3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(1)	Color	Technical	Yes	00004112 00004019	No	6
		Other Manufacturing Use Formulations	No		Yes	6
163.61-8(2)	Odor	Technical	Yes	00004112 00004019	No	6
		Other Manufacturing Use Formulations	No		Yes	6
163.61-8(3)	Melting Point	Technical	Yes	00004112 00004019	No	6
		Other Manufacturing Use Formulations	No		Yes	6
163.61-8(4)	Solubility	Technical	No		Yes	6
163.61-8(5)	Stability	Technical	Yes	00004112 00004019	No	6
163.61-8(6)	Octanol/Water Partition Coefficient	Technical	No		Yes	6

Table B (Continued)

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation(s)	Must Date Be Submitted Under FIFRA §3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(7)	Physical State	Technical and other Manufacturing Use Formulations	Yes	00004112 00004019	No	6
163.61-8(8)	Density or Specific Gravity	Technical and other Manufacturing Use Formulations	No		Yes	6
163.61-8(9)	Boiling Point	Technical	Yes	00004019 00004112	No	6
163.61-8(11)	pH	Technical	No		Yes	6
	Toxicology					
163.81-1	Acute Oral Toxicity	Non-technical Formulations	Yes	00004024	No	6
163.81-2	Acute Dermal formulations	Non-technical	Yes	00004024	No	6
163.81-4	Primary Eye Irritation	Non-technical	Yes	00004024	No	6
163.81-5	Primary Dermal Irritation	Non-technical	Yes	00004024	No	6

Table C PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
	Product Chemistry					
163.61-3	Product Identity and Disclosure of Ingredients	All Formulations	No		Yes	6
163.61-4	Description of Manufacturing Processes	All Formulations	No		Yes	24
163.61-5	Formulation of Unintentional Ingredients	All Formulations	No		Yes	24
163.61-6	Description and Certification of Ingredient Limits	All Formulations	No		Yes	6 (24)*
163.61-7	Product Analytical Methods/Data	All impregnated grains	Yes	00003978 and 00004020	No	6
		Other Formulations	No		Yes	6
163.61-8(1)	Color	On Technical	Yes	00004019 and 00004112	No	6
		On Formulations	No		Yes	6

*24 months permitted for submission of information on impurities present as less than 0.1% of total product. Information on impurities present at greater concentrations must be submitted within 6 months.

Table C (Continued)

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
1263.61-8(2)	Odor	On Technical	Yes	00004019 and 00004112	No	6
		On Formulations	No		Yes	6
163.61-8(7)	Physical State	On Technical	Yes	00004019 and 004112	No	6
		On Formulations	No		Yes	6
163.61-8(8)	Density/Specific Gravity	On Formulations	No		Yes	6
163.61-8(9)	Boiling Point	On Technical	No	00004019 and 00004112	No	6
163.61-8(11)	pH	On Technical	No		Yes	6
163.61-8(12)	Storage Stability	All Formulations	No		Yes	6
	<u>Toxicology</u>					
163.81-1	Acute Oral Toxicity	All Formulations	Yes	00004024	No	6

Table C (Continued)

GUIDELINES SECTION	NAME OF TEST	COMPOSITION CHARACTERISTICS	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D)?	Bibliographic Citation(s)	Must Date Be Submitted Reliance Under §3(c)(2)(B)?	Months Allowed Before Submission
163.81-3	Acute Inhalation	Dust Formulations	Yes		Yes	24
		Non-Dust Formulations	No		No	
163.81-5	Primary Dermal	Granular (impregnated Grain) Formulations	Yes	00004137 and 00004024	No	6
		Non-Granular Formulations	No		No	
163.82-4	Subchronic Inhalation Toxicity	Dusts without Protective Clothing Requirements	No		Yes	24
		All Other Formulations	No		No	

1,4-Dichloro-2,5 Dimethoxybenzene

(Chloroneb)

TABLE-A

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Guideline Section	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.81-1	Acute Oral Toxicity	food	yes	GS0007-010	no	6
		turf	yes		no	
163.81-2	Acute Dermal Toxicity	food	no		yes	6
		turf	no		yes	
163.81-3	Acute Inhalation Toxicity	food	no		yes	6
		turf	no		yes	
163.82-1	Subchronic Oral Dosing	food	yes	00001446 & 00001421 & 00004980	no	24
163.82-2	Subchronic 21-day Dermal Toxicity	food	yes	00001445	no	24
		turf	yes	00001445	no	
163.83-1	Chronic feeding	food	yes	00001422	yes	42
163.83-2	Oncogenicity	food	yes	00001422	yes	42
163.83-3	Teratogenicity	food	no		yes	24
		turf	no		yes	
163.83-4	Reproduction	food	no		yes	24
		turf	no		yes	
163.84-1	Mutagenicity	food	no		yes	24
		turf	no		yes	
163.85-1	Metabolism	food	yes	05001159 & 00001424	yes	24

TABLE-A

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Guidelines Section	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.62-7(b)	Hydrolysis	food	yes	GS0007-6	no	24
		turf	yes		no	
163.62-7(c)	Photodegradation	food	no		yes	24
		turf	no		yes	
163.62-8(b)	Aerobic Soil Metabolism	food	no		yes	24
		turf	no		yes	
163.62-8(c)	Anaerobic Soil Metabolism	food	no		yes	24
		turf	no		yes	
163.62-8(f)(2)	Effects of Microbes on Pesticides	food	yes	05001155 & 05001170	yes	24
		turf	yes		yes	
163.62-8(f)(3)	Effects of Pesticides on Microbes	food	yes	05001170 & 05001167 & 05001308 & 05001292	yes	24
		turf	yes			
163.62-8(g)	Activated Sludge	food	yes	GS0007-7	no	24
		turf	yes		no	
163.62-9(b)	Leaching	food	no		yes	24
		turf	no		yes	
163.62-9(d)	Adsorption/Desorption	food	no	00001426	yes	24
		turf	no		yes	
163.62-10(b)	Terrestrial Field Dissipation * (a)	food	yes		yes	24
		turf	yes		yes	24

* (a) Test on Typical Formulated Product

TABLE-A

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Guidelines Section	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.62-11(b)	Rotational Crop	food	no		yes	24
163.62-11(d)	Fish Accumulation	food	no		yes	24
		turf	no		yes	
163.71-1	Avian Single Dose	food	no		yes	6
	Oral LD 50 ** (a)	turf	no		yes	
163.71-2	Avian Dietary LC 50	food	yes	GS00007-001 &	no	6
	Mallard Duck &	turf	yes	GS00007-002	no	
	Bobwhite Quail ** (a)					
163.72-1	Fish Acute LC 50	food	yes	GS0007-003	yes	6
	Rainbow Trout &	turf	yes		yes	
	Bluegill ** (a)					
163.72-2	Acute Toxicity to	food	yes	GS00007-005	no	6
	Aquatic Invertebrates	turf	yes		no	
	** (a)					

** (a) Required on Technical Product

CHLORONEB

TABLE-B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guidelines Section	Name of Test	Composition Type	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-3	Product Identity & Disclosure of Ingrdients	Manufactur-ing Use Product	yes	GS00001428	no	6
163.61-4	Description of Manufacturing Process	" "	no		yes	24
163.61-5	Discussion on Formation of Unintentional Ingredients	" "	no		yes	24
163.61-6 *	Declaration & Certification of Ingredient Limits	" "	no		yes	6
163.61-7	Product Analytical Methods & Data	" "	no		yes	6
163.61-8(1)	Color	Technical Product	yes	00001444	no	6
163.61-8(2)	Odor	" "	yes	00001444	no	6
163.61-8(3)	Melting Point	" "	yes	00001444	no	6
163.61-8(4)	Solubility	" "	yes	00001444	no	6
163.61-8(5)	Stability	" "	yes	00001444	no	6
163.61-8(6)	Octanal/Water Partition Coefficient	" "	no		yes	6

TABLE-B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guidelines Section	Name of Test	Composition Type	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(7)	Physical State	Technical & Manufacturing Use Product	yes	00001444	no	6
163.61-8(8)	Density or Specific	" "	yes	00001444	no	6
163.61-8(9)	Boiling Point	" "	yes	00001444	no	6
163.61-8(10)	Vapor Pressure	" "	yes	00001444	no	6
163.61-8(11)	pH	" "	yes	00001444	no	6
163.61-8(12)	Storage Stability	Manufacturing Use Product	no		yes	6
163.61-8(13)	Flammability	" "	no		yes	6
163.61-8(14)	Oxdizing or Reducing Action	" "	no		yes	6
163.61-8(15)	Explosiveness	" "	no		yes	6
163.61-8(18)	Corrosion Characteristics	" "	no		yes	6
163.81-1	Acute Oral Toxicity	Manufacturing Use Product	yes	GS0007-010	no	6
163.81-2	Acute Dermal Toxicity	" "	no		yes	6

TABLE-B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guidelines Section	Name of Test	Composition Type	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.81-3	Acute Inhalation Toxicity	Manufacturing Use Product	no		no	6
163.81-4	Primary Eye Irritation	" "	yes	GS0007-011	no	6
163.81-5	Primary Dermal Irritation	" "	yes	GS0007-012	no	6
163.81-6	Dermal Sensitization	" "	no		yes	6

* Any information on impurities of less that 0.1% need not be submitted for 24 months.

CHLORONEB

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS

Guidelines Section	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-3	Product Identity & Disclosure of Ingredient	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-4	Description of Manufacturing Process	Wettable Powder	no		yes	24
		granular	"			
		dust	"			
163.61-5	Discussion of Formation of Unintentional Ingredients	Wettable Powder	no		yes	24
		granular	"			
		dust	"			
163.61-6 *	Declaration & Certification of of Ingredient Limits	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-7	Product Analytical Methods and Data	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(1)	Color (a)	Wettable Powder	no		yes	6
		granular	"			
		dust	"			

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS

Guidelines Section	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(2)	Odor (a)	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(7)	Physical State (a)	Wettable Powder	yes	00001444	no	6
		granular	"			
		dust	"			
163.61-8(8)	Density or Specific Gravity (a)	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(9)	Boiling Point (a)	Wettable Powder	yes	00001444	no	6
		granular	"			
		dust	"			
163.61-8(10)	Vapor Pressure (a)	Wettable Powder	yes	00001444	no	6
		granular	"			
		dust	"			
163.61-8(11)	pH (a)	Wettable Powder	no		yes	6
		granular	"			
		dust	"			

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Guidelines Section	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(12)	Storage Stability	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(13)	Flammability	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(14)	Oxidizing or Reducing Action	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(15)	Explosiveness	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(16)	Miscibility	Wettable Powder	no		yes	6
		granular	"			
		dust	"			
163.61-8(17)	Viscosity	Wettable Powder	no		yes	6
		granular	"			
		dust	"			

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS

Guidelines Section	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.61-8(18)	Corrosion Characteristics	Wettable Powder	no		yes	6
		granular	-			
		dust	-			
163.81-1	Acute Oral Toxicity	10% dust	no		yes	6
		6.25-10% granular	yes	00001495	no	
		65% Wettable Powder	no		yes	
163.81-2	Acute Dermal Toxicity	10% dust	no		yes	6
		6.25-10% granular	no		yes	
		65% Wettable Powder	no		yes	
163.81-3	Acute Inhalation Toxicity	10% dust	no		yes	6
		6.25-10% granular	no		yes	
		65% Wettable Powder	no		yes	
163.81-4	Primary Eye Irritation	10% dust	no		yes	6
		6.25-10% granular	no		yes	
		65% Wettable Powder	no		yes	

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS

Guidelines Section	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement?	Bibliographic Citation	Must Data be Submitted under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.81-5	Primary Dermal Irritation	10% dust	no		yes	6
		6.25-10% granular	yes	00001495	no	
		65% Wettable Powder	no		yes	
163.81-6	Dermal Sensitization	10% dust	no		yes	6
		6.25-10% granular	no		yes	
		65% Wettable Powder	no		yes	

* Any information on impurities of less than 0.1% need not be submitted for 24 months.

(a) Required of both the formulated and the technical product.

2-chloro-N-(2-ethyl-6-methylphenyl)

-N-(2-methoxy-1-methylethyl) acetamide

(Metolachlor)

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Table A

Guideline Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D) Cite Data in Standard's Bibliography	Bibliographic Citation	Must Data Be Submitted Under FIFRA §3(c)(2)(B)	Months Allowed Before Submission
163.62-7(b)	Hydrolysis	Agricultural-corn sorghum, peanuts, soybeans	Yes		No	
-7(c)	Photodegradation	"	"		"	
163.62-8(b)	Aerobic soil metabolism	"	"		"	
-8(c)	Anaerobic soil metabolism	"	"		"	
163.62-8(f)(2)	Effects of microbes on pesticides	"	"		"	
-8(f)(3)	Effects of pesticides on microbes	"	"		"	
-8(g)	Activated sludge metabolism	"	No		Yes	24
163.62-9(b)	Leaching	"	Yes		No	
-9(d)	Adsorption/desorption	"	No		Yes	24
163.62-10(b)	Terrestrial field dissipation	"	Yes		No	
163.62-11(b)	Rotational crop	"	Yes		Yes	24
-11(d)	Fish accumulation	"	Yes		No	
	Actual field residue monitoring studies at two watershed sites to be approved by the Agency	"	No		Yes	24

METOLACHOR

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Table A

Guidelines Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D) Cite Data in Standard's Bibliography	Bibliographic Citation	Must Data Be Submitted Under FIFRA §3(c)(2)(B)	Months Allowed Before Submission
163.71-1	Avian single-dose oral LD_{50}	Agricultral-corn sorghum peanuts, soybeans	No		Yes	6
-2	Avian dietary LC_{50} mallard	"	Yes		No	
	bobwhite quail		Yes		No	
-4	Avian reproduction mallard and	"	Yes		No	
	bobwhite		Yes		No	
163.72-1	Fish acute LC_{50} rainbow trout and	"	Yes		No	
	bluegill	"	Yes		No	
-2	Acute toxicity to aquatic Invertebrates	"	Yes		No	
-4	Embryolarvae and life cycle studies/fish and aquatic vertebrates	"	Yes		No	

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

Table A

Guidelines Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA §3(c)(1)(D) Cite Data in Standard's Bibliography	Bibliographic Citation	Must Data Be Submitted Under FIFRA §3(c)(2)(B)	Months Allowed Before Sub-mission
163.81-1	Acute oral toxicity	Agricultural-corn, sorghum peanuts, soybeans	Yes		No	
-2	Acute dermal toxicity	"	Yes		No	
-3	Acute inhalation toxicity	"	Yes		No	
163.82-1	Subchronic oral dosing	"	Yes		No	
	Evaluation for rat pathology study	"	No		Yes	24
-2	Subchronic 21-day dermal toxicity	"	Yes		No	
163.83-1	Chronic feeding	"	No		Yes	9/1/83
-2	Oncogenicity, mouse and rat study completed	"	Yes		No	
	2nd study other than mouse	"	No		Yes	42
	2nd study in mouse in progress	"	No		Yes	11/1/82
-3	Teratogenicity (1st species completed)	"	Yes		No	
	2nd species in progress	"	No		Yes	11/1/80
-4	Reproduction Completed study	"	Yes		No	
	2nd study in progress	"	No		Yes	6/1/82
163.84-1	Mutagenicity	"	Yes		No	
163.85-1	Metabolism	"	Yes		No	

PRODUCT-SPECIFIC SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS

Table B

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.61-3	Product Identity and disclosure of Ingredients	Technical	Yes		No	
-4	Description of manufacturing process	"	"		"	
-5	Discussion on formation of unintentional ingredients	"	"		"	
-6	Declaration and certification of ingredient limits	"	"		"	
-7	Product analytical methods and data	"	"		"	
163.61-8(1)	Color	"	"		"	
-8(2)	Odor	"	"		"	
-8(4)	Solubility	"	"		"	
-8(5)	Stability	"	"		"	
-8(6)	Octanol/water partition coefficient	"	No		Yes	6 months
-8(7)	Physical State	"	Yes		No	

METOLACHOR

PRODUCT-SPECIFIC SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Table B cont'd

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
-8(8)	Density or specific gravity	Technical	Yes		No	
-8(9)	Boiling Point	"	"		"	
-8(10)	Vapor pressure	"	"		"	
-8(12)	Storage Stability	"	"		"	
-8(13)	Flammability	"	No		Yes	6 mos.
-8(14)	Oxidizing or reducing action	"	"		"	6 mos.
-8(15)	Explosiveness	"	"		"	6 mos.
-8(17)	Viscosity	"	"		"	6 mos.
-8(18)	Corrosion characteristics	"	"		"	6 mos.

PRODUCT-SPECIFIC SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

Table B cont'd

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.81-1	Acute oral toxicity *	Technical	Yes		No	
-2	Acute dermal toxicity *	"	"		"	
-3	Acute inhalation toxicity *	"	"		"	
-4	Primary eye irritation *	"	"		"	
-5	Primary dermal irritation *	"	"		"	
-6	Dermal sensitization *	"	"		"	

* Test on manufacturing-use product

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Table C

Guidelines Citation	Name of Test	Composition Characteristics	Does EPA Have Data To In Satisfy This Requirement ?	Biblio-Graphic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B) ?	Months Allowed Before Sub-mission
163.61-3	Product identity and disclosure of ingredients	8 lb. E. C.	Yes		No	
-4	Description of manufacturing process	"	"		"	
-6	Declaration and certification of ingredient limits	"	"		"	
163.61-8(1)	Color	"	No		Yes	6 mos.
-8(2)	Odor	"	"		"	6 mos.
-8(7)	Physical State	"	Yes		No	
-8(8)	Density or specific gravity	"	"		"	
-8(9)	Boiling Point	"	"		"	
-8(10)	Vapor pressure	"	"		"	
-8(11)	pH	"	"		"	
-8(12)	Storage stability	"	"		"	
-8(13)	Flammability	"	"		"	
-8(14)	Oxidizing or reducing action	"	"		"	
-8(15)	Explosiveness	"	No		Yes	6 mos.
-8(16)	Miscibility	"	Yes		No	
-8(17)	Viscosity	"	"		"	
-8(18)	Corrosion characteristics	"	"		"	

METOLACHOR

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Table C cont'd

Guidelines Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.61-3	Product Identity and disclosure of ingredients	61b. E. C.	Yes		No	
-4	Description of manufacturing process	"	"		"	
-6	Declaration and certification of ingredient limits	"	"		"	
163.61-8(1)	Color	"	No		Yes	6 mos
-8(2)	Odor	"	"		"	6 mos.
-8(7)	Physical State	"	Yes		No	
-8(8)	Density or specific gravity	"	"		"	
-8(9)	Boiling Point	"	"		"	
-8(10)	Vapor pressure	"	"		"	
-8(11)	pH	"	"		"	
-8(12)	Storage stability	"	"		"	
-8(13)	Flammability	"	"		"	
-8(14)	Oxidizing or reducing action	"	"		"	
-8(15)	Explosiveness	"	Yes		No	
-8(16)	Miscibility	"	"		"	
-8(17)	Viscosity	"	"		"	
-8(18)	Corrosion characteristics	"	"		"	

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Table C cont'd

Guidelines Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirements ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.81-1	Acute oral toxicity	8 lb. E. C.	Yes		No	
-2	Acute dermal toxicity	"	"		"	
-3	Acute inhalation toxicity	"	No		Yes	6 mos.
-4	Primary eye irritation	"	Yes		No	
-5	Primary dermal irritation	"	"		"	

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

Table C cont'd

Guidelines Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirements ?	Bibliographic Citation	Must Data Be Submitted Under FIFRA § 3(c)(2)(B) ?	Months Allowed Before Submission
163.81-1	Acute oral toxicity	6 lb. E. C.	Yes		No	
-2	Acute dermal toxicity	"	"		"	
-3	Acute inhalation toxicity	"	"		"	
-4	Primary eye irritation	"	"		"	
-5	Primary dermal irritation	"	"		"	

5-Ethoxy-3-trichloromethyl-1,2,4-thiadiazole

(Terrazole)

TABLE A[1]

GENERIC DATA REQUIREMENTS FOR MANUFACTURING - USE AND END - USE
PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D)

GUIDELINES SECTION	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA § 3(c)(1)(D)	Bibliographic Citation	Must Data be Submitted FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.81-1	Acute Oral Toxicity on Technical	Ornamentals & Turf	Yes	00001555 and 00001586 and 00001792	No	
163.81-2	Acute Dermal Toxicity on Technical	Ornamentals & Turf	Yes	00002227	No	
163.81-3	Acute Inhalation Toxicity on Technical	Ornamentals & Turf	Yes	00001591	Yes	6
163.82-1	Subchronic Oral Dosing	Ornamentals & Turf	Yes	00001588 and 00001589 and 00001600 and 00001605 and 00001697	Yes	24
163.82-2	Subchronic 21-Day Dermal Toxicity	Ornamentals & Turf	Yes	00001571	Yes	24
163.83-1	Chronic Feeding	Ornamentals & Turf	Yes	00001600	Yes	42
163.83-2	Oncogenicity	Ornamentals & Turf	Yes	00001600	Yes	42
163.83-3	Teratogenicity	Ornamentals & Turf	Yes	GS0009-033	Yes	24

GUIDELINES SECTION	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA § 3(c)(1)(D)	Bibliographic Citation	Must Data be Submitted FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.83-4	Reproduction	Ornamentals & Turf	Yes	00001698		
163.84-1	Mutagenicity	Ornamentals & Turf	Yes	GS00009-32	Yes	24
163.85-1	Metabolism	Ornamentals & Turf	Yes	0000097 or 00001577 or 00001599 or 00001601 or 05004729	Yes No	
163.62-7(b)	Hydrolysis	Ornamentals & Turf	Yes	00001650 or 00001652	No	
163.62-8(c)	Photodegradation	Ornamentals & Turf	No		Yes	24
163.62-8(b)	Aerobic Soil Metabolism	Ornamentals & Turf	Yes	00001657 or 00001662 or 00001664	Yes	24
163.62-8(c)	Anaerobic Soil Metabolism	Ornamentals & Turf	Yes	00001657	No	
163.62-8(f)(2)	Effects of Microbes on Pesticides	Ornamentals & Turf	Yes	00001567 or 00001664	Yes	24
163.-8(g)	Activated Sludge Metabolism	Ornamentals & Turf	Yes	GS0009-39	No	
163.62-9(b)	Leaching	Ornamentals & Turf	Yes	00001655 and 05001190	Yes	24

GUIDELINES SECTION	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA § 3(c)(1)(D)	Bibliographic Citation	Must Data be Submitted FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.62-9(c)	Volatility	Ornamentals & Turf	No		Yes	24
163.62-9(d)	Adsorption/ Desorption	Ornamentals & Turf	No		Yes	24
163.62-10(b)	Terrestrial Field Dissipation	Ornamentals & Turf	Yes	00001659 or 00001660 or 00001661 or 00001763 or	Yes	24
163.62-11(d)	Fish Accumulation	Ornamentals & Turf	Yes	00001663	Yes	24
163.71-1	Avian Single-dose LD_{50}	Ornamentals & Turf	Yes	00002238 and 00003276	No	
163.72-1	Avian Dietary LC_{50}	Ornamentals & Turf	No		Yes	6
163.72-1	Fish Acute LC_{50}	Ornamentals & Turf	Yes	00001703	No	
163.72-2	Acute Toxicity to Aquatic Invertebrate	Ornamentals & Turf	No		Yes	6

TABLE B[1]

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.61-3	Product Identity and Disclosure of Ingredients	Manufacturing-Use Product	Yes	GS0009-048	No	
163.61-4	Description of Manufacturing Process	Manufacturing-Use Product	Yes	GS0009-048	No	
163.61-5	Discussion on Formation of Unintentional Ingredients	Manufacturing-Use Product	Yes	GS0008-035	No	
163.61-6	Declaration & Certification of Ingredients Limits	Manufacturing-Use Product	Yes	GS0009-035	No	
163.61-7	Product Analytical Methods & Data	Manufacturing-Use Product	Yes	GS0009-048	No	
163.61-8(1)	Color	Technical	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(2)	Odor	Technical	Yes		No	
163.61-8(4)	Solubility	Technical	Yes		No	
163.61-8(5)	Stability	Technical	Yes		No	
163.61-8(6)	Octanol/water Partition Coefficient	Technical	Yes		No	

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.61-8(7)	Physical State	Technical & Manufacturing Use	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(8)	Density or Specific Gravity	Technical & Manufacturing Use	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(9)	Boiling Point	Technical & Manufacturing Use	Yes	00001553 and 00001556 and 00001769	No	
163.61-8(10)	Vapor Pressure	Technical & Manufacturing Use	Yes	00002232	No	
163.61-8(11)	pH	Technical & Manufacturing Use	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(12)	Storage Stability	Manufacturing-Use Product	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(13)	Flammability	Manufacturing-Use Product	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(14)	Oxidizing or Reductive Action	Manufacturing-Use Product	Yes	00001553 and 00001556 and 00001760	No	
163.61-8(15)	Explosiveness	Manufacturing-Use Product	No		Yes	6

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.61-8(16)	Miscibility	Manufacturing-Use Product	No		Yes	6
163.61-8(17)	Viscosity	Manufacturing-Use Product	Yes	00001553 and 00001556 and 00001760 and	No	
163.61-8(18)	Corrosion Characteristics	Manufacturing-Use Product	Yes	00001553 and 00001556 and 00001760 and	No	
163.81-1	Acute Oral Toxicity	Manufacturing-Use Product	Yes	00001555 and 00001586 and 00001792	No	
163.81-2	Acute Dermal Toxicity	Manufacturing-Use Product	Yes	00002227	No	
163.81-3	Acute Inhalation Toxicity	Manufacturing-Use Product	Yes	00001591	Yes	6
163.81-4	Primary Eye Irritation	Manufacturing-Use Product	Yes	00001590	No	
163.81-5	Primary Dermal Irritation	Manufacturing-Use Product	Yes	00001593	Yes	6
163.81-6	Dermal Sensitzation	Manufacturing-Use Product	Yes	GS0009-030	Yes	6

TABLE C

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.61-3	Product Identity and Disclosure of Ingredients	All Types	No		Yes	6
163.61-4	Description of Manufacturing Process	All Types	No		Yes	24
163.61-5	Discussion on Formation of Unintentional Ingredients	All Types	No		Yes	6
163.61-6	Declaration and Certification of Ingredient Limits	All Types with greater than .1% Impurities	No		Yes	6
		All types with less than .1% Impurities	No		Yes	24
163.61-7	Product Analytical Methods and Data	All Types	No		Yes	6
163.61-8(1)	Color of Formulation and Technical	All Types	No		Yes	6
163.61-8(2)	Odor of Formulation and Technical	All Types	No		Yes	6
163.61-8(7)	Physical State of Formulation and Technical	All Types	Yes	GS0009-036 and 00001760	No	
163-61-8(8)	Density or Specific Gravity of Formulation and Technical	All Types	No		Yes	6

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.61-8(9)	Boiling Point of Formulation and Technical	25% EC	No		Yes	6
		4 lb/Gallon EC	No		Yes	6
163.61-8(10)	Vapor Pressure of Formulation and Technical	All Types	Yes	00002232	No	
163.61-8(11)	pH of Formulation and Technical	All Types	Yes	GS0009-035	No	
163.61-8(12)	Storage Stability	All Types	No		Yes	6
163.61-8(13)	Flammability	25% EC	No		Yes	6
		4 lb/Gallon EC	No		Yes	6
163.61-8(14)	Oxidizing or Reducing Action	All Types	No		Yes	6
163.61-8(15)	Explosiveness	All Types	No		Yes	6
163.61-8(16)	Miscibility	25% EC	No		Yes	6
		4 lb/Gallon EC	No		Yes	6
163.61-8(17)	Viscosity	25% EC	No		Yes	6
		4 lb/Gallon EC	No		Yes	6
163.61-8(18)	Corrosion Characteristics	All Types	No		Yes	6
163.81-1	Acute Oral Toxicity	30% WP/D and 35% WP	Yes	00001592	No	
		25% EC	No		Yes	6
		4 lb./Gallon EC	Yes	00001828	No	
		5% Granular	Yes	GS00009-034	No	
163.81-2	Acute Dermal Toxicity	30% WP/D and 35% WP	Yes	00001593	No	
		25% EC	No		Yes	6

GUIDELINES SECTION	Name of Test	Composition Characteristics	Does EPA Have Data to Satisfy this Requirement	Bibliographic Citation	Must Data be Submitted Under FIFRA § 3(c)(2)(B)	Months Allowed Before Submission
163.81-2	Acute Dermal Toxicity	4 lb./Gallon EC	Yes	00001831	No	
		5% Granular	Yes	GS0009-034	No	
163.81-3	Acute Inhalation Toxicity	30% WP/D and 35% WP	No		Yes	6
		25% EC	No		Yes	6
		4 lb./Gallon EC	Yes	00001828	Yes	6
		5% Granular	Yes	GS0009-035		
163.81-4	Primary Eye Irritation	30% WP/D and 35% WP	No		Yes	6
		25% EC	Yes	GS0009-031	Yes	6
163.81-5	Primary Dermal Irritation	30% WP/D and 35% WP	No		Yes	6
		25% EC	No		Yes	6
		4 lb./Gallon EC	Yes	00001828	No	
		5% Granular	Yes	GS0009-034	No	
163.81-6	Dermal Sensitization	All Types	No		Yes	6

3-(alpha-acetonylfurfuryl)-4-hydroxycoumarin)

(Fumarin^{R})

TABLE A

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D) CONTAINING FUMARIN OR THE SODIUM SALT OF FUMARIN

GUIDELINES CITATION	NAME OF TEST	USE PATTERN	MUST APPLICANT ACKNOWLEDGE RELIANCE UNDER FIFRA §3(c)(1)(D)	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER FIFRA §3(c)(2)(B)	MONTHS ALLOWED BEFORE SUBMISSION
163.81-1	Acute Oral LD_{50}(1)	All Uses	No		Yes	6
163.81-2	Acute Dermal(1) LD50	All Uses	No		Yes	6
163.81-3	Acute(1) Inhalation LC_{50}	All Uses	No		Yes	6
163.81-4	Primary Eye(1) Irritation	All Uses	No		Yes	6
163.81-5	Primary Dermal(1) Irritation	All Uses	No		Yes	6
163.81-6	Dermal(1) Sensitization	All Uses	No		Yes	6
163.82-2	Subchronic Dermal(1)	All Uses	No		Yes	24
163.83-3	Teratology(1)	All Uses	No		Yes	24
163.84-1,2,3,4	Mutagenicity(1)	All Uses	No		Yes	24

(1) Required on Technical (active ingredient).

TABLE A - Continued

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D) CONTAINING FUMARIN OR THE SODIUM SALT OF FUMARIN

GUIDELINES CITATION	NAME OF TEST	USE PATTERN	MUST APPLICANT ACKNOWLEDGE RELIANCE UNDER FIFRA §3(c)(1)(D)	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER FIFRA §3(c)(2)(B)	MONTHS ALLOWED BEFORE SUBMISSION
163.71-1	Avian Single(2) Dose LD_{50}	All uses except dumps	No		No	-
		Dumps	No		Yes	6
163.71-2	Subacute Dietary(2) LC50 Mallard and Bobwhite	All uses except dumps	No		No	-
		Dumps	No		Yes	6
163.71(c)(3)	Fish 96 Hour LC_{50}(2) Rainbowtrout Bluegill	All uses except dumps	No		No	-
		Dumps	No		Yes	6
163.72-2	Aquatic(2) Invertebrate LC_{50}	All uses except dumps	No		No	-
		Dumps	No		Yes	6

(2) Required on Technical Fumarin and Technical Sodium Salt of Fumarin (Purest form of technical).

TABLE A - Continued

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS NOT EXEMPTED BY FIFRA SECTION 3(c)(2)(D) CONTAINING FUMARIN OR THE SODIUM SALT OF FUMARIN

GUIDELINES CITATION	NAME OF TEST	USE PATTERN	MUST APPLICANT ACKNOWLEDGE RELIANCE UNDER FIFRA §3(c)(1)(D)	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER FIFRA §3(c)(2)(B)	MONTHS ALLOWED BEFORE SUBMISSION
163.71-3	Dietary LC_{50}(2) Target Rodent Species	All uses except dumps	No		No	-
		Dumps	No		Yes	12
163.71-3	Primary Dietary(2) LC50 on Carnivores	All uses except dumps	No		No	-
		Dumps	No		Yes	12
163.70-1(c)	Secondary Toxicity(2) Feeding Study on Carnivores	All uses except dumps	No		No	-
		Dumps	No		Yes	12
163.70-1(c)	Secondary Toxicity(2) Feeding Study on Raptors	All uses except dumps	No		No	-
		Dumps	No		Yes	12

(2) Required on Technical Fumarin and Technical Sodium Salt of Fumarin (purest form of Technical).

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSION
163.61-3	Product Identity Disclosure of Ingredients	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-4	Description of Manufacturing Process	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-5	Discussion on Formation of Unintentional Ingredients	TECHNICAL Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-6	Declaration and Certification of Ingredient Limits	Technical Fumarin Sodium Salt	No		Yes	6(24[1])
		Technical Fumarin	No		Yes	6(24[1])
		Fumarin (50%, 10%, 0.5%)	No		Yes	6(24[1])
163.61-7	Product Analytical Methods and Data	Technical Fumarin Sodium Salt	Yes	00001200	No	--
		Technical Fumarin	Yes	00001200	No	-
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(1)	Color[2]	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	Yes	00001199	No	-
		Fumarin (50%, 10%, 0.5%)	No		Yes	6

(1) Any impurities at 0.1% or less - Information need not be submitted until 24 months.
(2) Required on both the formulated and the technical (purest form of active ingredient) products.

TABLE B - CONTINUED

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSIC
163.61-8(2)	Odor(2)	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	Yes	00001199	No	-
		Fumarin (50%, 10%, 0.5%)	No		No	-
163.61-8(3)	Melting Point	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	Yes	00001199	No	-
		Fumarin (50%, 10%, 0.5%)	No		No	-
163.61-8(4)	Solubility	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		No	-
163.61-8(6)	Octanol/Water Partition Coefficient	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		No	-
163.61-8(7)	Physical State	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	Yes	00001199	No	-
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(8)	Density or Specific Gravity(2)	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6

(2) Required on both the formulated and the technical (purest form of active ingredient) products.

TABLE B - CONTINUED

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSION
163.61-8(9)	Boiling Point	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(10)	Vapor Pressure	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(11)	pH	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(12)	Storage Stability	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(13)	Flammability	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(14)	Oxidizing or Reducing Action	Technical Fumarin Sodium Salt	No		No	-
		Technical Fumarin	No		No	-
		Fumarin (50%, 10%, 0.5%)	No		Yes	6

TABLE II - CONTINUED

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSION
163.61-8(15)	Explosiveness	Technical Fumarin Sodium Salt	No		No	-
		Technical Fumarin	No		No	-
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.61-8(16)	Corrosion Characteristics	Technical Fumarin Sodium Salt	No		Yes	6
		Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.71-1	Avian Single-(3) Dose Oral LD_{50}	Technical Fumarin or its Sodium Salt	No		No	6
		Fumarin (50%, 10%, 0.5%)	No		No	6
163.71-2	Avian Dietary(3) LC_{50} Mallard & Bob White Quail	Technical Fumarin or its Sodium Salt	No		No	6
		Fumarin (50%, 10%, 0.5%)	No		No	6
163.72-1	Fish Acute LC_{50}(3) Rainbow Trout and bluegill	Technical Fumarin or its Sodium Salt	No		No	6
		Fumarin (50%, 10%, 0.5%)	No		No	6
163.72-2	Acute Toxicity(3) to Aquatic Invertebrate	Technical Fumarin or its Sodium Salt	No		No	6
		Fumarin (50%, 10%, 0.5%)	No		No	6

(3) These fish and wildlife studies are required on Technical (purest form active ingredient) for use of product, involving dump sites.

TABLE 8 - CONTINUED

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSION
163.71-3	Dietary LC_{50}(3) Target Rodent Species	Technical Fumarin or its Sodium Salt	No		No	12
		Fumarin (50%, 10%, 0.5%)	No		No	12
163.72-3	Primary Dietary(3) LC_{50} on Carnivores	Technical Fumarin or its Sodium Salt	No		No	12
		Fumarin (50%, 10%, 0.5%)	No		No	12
163.70-1(c)	Secondary toxi-(3) city Feeding Study on Carnivores	Technical Fumarin or its Sodium Salt	No		Yes	12
		Fumarin (50%, 10%, 0.5%)	No		Yes	12
163.70-1(c)	Secondary toxi-(3) city Feeding study on Raptors	Technical Fumarin or its Sodium Salt	No		Yes	12
		Fumarin (50%, 10%, 0.5%)	No		Yes	12
163.81-1	Acute Oral LD_{50}(4) Toxicity	Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.81-2	Acute Dermal LC_{50}(4) Toxicity	Technical Fumarin	No		Yes	6
		Fumarin (50%, 10%, 0.5%)	No		Yes	6

(3) These fish and wildlife studies are required on Technical (purest form of the active ingredient) for use of products involving dump sites.

(4) The Agency can use data on Technical Fumarin to satisfy this requirement for the 50% and 10% formulations. The registrant must either cite or submit these data.

TABLE II - CONTINUED

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUIREMENT	BIBLIOGRAPHIC CITATION	MUST DATA BE SUBMITTED UNDER § 3(c)(2)(B) FIFRA	MONTHS ALLOWED BEFORE SUBMISSION
163.81-3	Acute Inhalation[4]	Technical Fumarin	No		Yes	6
	LC_{50} Toxicity	Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.81-4	Primary Eye[4]	Technical Fumarin	No		Yes	6
	Irritation	Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.81-5	Primary Dermal[4]	Technical Fumarin	No		Yes	6
	Irritation	Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.81-6	Dermal[4]	Technical Fumarin	No		Yes	6
	Sensitization	Fumarin (50%, 10%, 0.5%)	No		Yes	6
163.83-2	Sub-Chronic Dermal	Technical Fumarin	No		Yes	24
163.83-3	Teratology	Technical Fumarin	No		Yes	24
163.84-1, 2,3,4	Mutagenicity	Technical Fumarin	No		Yes	24

(4) The Agency can use data on Technical Fumarin to satisfy this requirement for the 50% and 10% formulations. The registrants must either cite or submit these data.

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

TABLE C

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUEST?	BIBLIO-GRAPHICS CITATION	Must Data BE SUBMITTED UNDER FIFRA § 3(c)(2)(B)	MONTHS ALLOWED BEFORE SUBMISSION
163.61-3	Product identify and disclosure of ingredients	Fumarin	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-4	Description of manufacturing process	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-6	Certification limits of Active Ingredient	FUMARIN	No		Yes	6 or 24 (1)
		FUMARIN SODIUM SALT	No		Yes	6 or 24 (1)
-8(1)	Color	FUMARIN READY	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-8(2)	Odor	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
163.61-8(4)	Solubility	Fumarin	No		No	
		FUMARIN SODIUM SALT	No		Yes	6
-8(7)	Physical State	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-8(8)	Density or Specific Gravity	FUMARIN	No		Yes	6
-8(9)	Boiling Point	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		No	
-8(10)	Vapor Pressure	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		No	
163.61-8(11)	pH	Fumarin	No		Yes	6
		FUMARIN SODIUM SALT LIQUID BAITS	No		Yes	6
-8(12)	Storage Stability	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-8(13)	Flammability	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
-8(14)	Oxidizing reducing action	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6

(1) Any impurities at 0.1% or less. Information need not be submitted until 24 months.

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS

TABLE C cont'd

GUIDELINES CITATION	NAME OF TEST	COMPOSITION CHARACTERISTICS	DOES EPA HAVE DATA TO SATISFY THIS REQUEST?	BIBLIO-GRAPHICS CITATION	Must Data BE SUBMITTED UNDER FIFRA § 3(c)(2)(B)	MONTHS ALLOWED BEFORE SUBMISSION
-8(15)	Explosiveness	FUMARIN	No		Yes	6
		FUMARIN SODIUM SALT				6
163.61-8(16)	Corrosion characteristics	Fumarin				6
		FUMARIN SODIUM SALT				6
163.96-10	Efficacy	FUMARIN	Refer to Appendix VI for these requirements			6
		FUMARIN SODIUM SALT	Refer to Appendix VI for these requirements			6
163.81-1	Acute Oral LD50 Toxicity (2)	FUMARIN (0.5%, 0.025%)	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
163.81-2	Acute Dermal LD50 Toxicity	FUMARIN (0.5%, 0.025%)	No		Yes (2)	6
		FUMARIN SODIUM SALT	No		Yes (3)	6
163.81-3	Acute Inhalation LC50 Toxicity (2)	FUMARIN (0.5%, 0.025%)	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
63.81-4	Primary Eye Irritation	FUMARIN (0.5%, 0.025%)	No		Yes (4)	6
		FUMARIN SODIUM SALT	No		Yes (2)	6
63.81-5	Primary Dermal Irritation (2)	FUMARIN (0.5%, 0.025%)	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6
63.81-6	Dermal Sensitization (2)	FUMARIN (0.5%, 0.025%)	No		Yes	6
		FUMARIN SODIUM SALT	No		Yes	6

(2) The Agency can use data on 0.5% Fumarin to satisfy this requirement. The registrant must cite these data or submit his own data.

(3) This study will be required unless a dissociation study under pH conditions comparable to skin epidermis shows that the Salt readily dissociates into Fumarin and Sodium Ion. If not required, Footnote 2 would apply.

(4) For 0.5% Fumarin products, one test will be required. For 0.025% granular Fumarin products, at least one representative formulation shall be tested. Registrants of these products should refer to Attachment D (Registrants with Pesticide Products Containing the Active Ingredient) to determine if their products are considered granular formulations. If serious problems arise, all formulations must be tested to assure proper labeling and safety to consumers and formulators. (These tests are not required for products whose pH is less than 3 or greater than 12.)

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to maintain the registration of your product(s). All this data must be submitted not later than 6 months after you receive this Guidance Package.

The tables entitled "Product-Specific Data Requirements for Manufacturing-Use Products" and "Product-Specific Data Requirements for End-Use Products," which appear as Tables B and C of this Guidance Package, permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases the Tables may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, we encourage you to elect to cite that data in lieu of generating and submitting new data. (You must comply with FIFRA Section 3(c)(1)(D) if you elect to cite existing data; see Section II of this Guidance Package.)

The Tables also indicate that in some cases, a product-specific data requirement for a group of similar products can be satisfied by a single test.

Your application for registration must include a completed copy of the form entitled "Product-Specific Data Report" (Appendix II-2), stating the methods you are using to comply with the product-specific data requirements.

V. Submission of Revised Labeling, Classification, and Packaging Information

The Agency has determined to require applicants for registration to amend their product's labeling order to insure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application for reregistration, you must submit draft labeling revised to be consistent with: your product-specific data; the precautionary statements and use directions described in Chapter II* of the Registration Standard; and the regulations concerning classification [40 CFR § 162.11(c)], packaging [40 CFR § 162.16], and labeling [40 CFR § 162.10], as indicated by the following paragraphs of this section of the Guidance Package. The labeling must be submitted within 6 months of your receipt of this Guidance Package.

If you fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel your registration under FIFRA § 6(b)(1).

* For Fumarin, the use directions are found in Chapter IV of the Registration Standard.

A. Label Contents

In 40 CFR Section 162.10 (Appendix V-1) it is required that specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Leeway for product individuality is provided in format labels, but only with the recognition that the label is a legal document to instruct the user on use and safety. Items listed below are keyed to Tables D, E, and F (Appendix V-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. In certain instances, the name of a product may be considered a claim for the product, and will not be accepted if it represents claims which may be false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The company name and address of the producer, and the registrant or person for whom material is produced is required on the label. It is preferred that the name and address be located at the bottom of the front panel, or at the end of the label text. If the registrant is not the producer, the name on the label must be qualified by "packaged for xxx," "Distributed by

xxx," or similar statements as appropriate. See Appendix V-1. [40 CFR §162. 10(c).]

Item 3. NET CONTENTS - A net content statement is required on all labels. It is preferred that it be located at the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net content may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. PRODUCT REGISTRATION NUMBER - The registration number assigned to the pesticide product at the time of registration must appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on the part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. PRODUCING ESTABLISHMENT REGISTRATION NUMBER - The producing establishment registration number, preceded by the phrase "EPA Est," of the final establishment at which the product was produced, may appear in any suitable location on the label or immediate container, but not on the cap or lid of the container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6A. INGREDIENT STATEMENT - An ingredient statement which contains the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients are required on the front panel. It is preferred that it be located immediately below the product name. The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text. See Appendix V-1. [40 CFR §162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For agricultural liquid formulations, the pounds per gallons of active ingredient must be indicated on the label.

Item 7. FRONT PANEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations. It should be noted that proposed labeling guidelines require a minimum 8 point (3mm) type size for all print on a label. When the Guidelines are finalized, the below list may be modified accordingly.

Size of label on front panel in square inches	Signal Word as Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	8 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel, immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSS BONES AND WORD "POISON" - Refer to the registration standard to determine if the skull and cross bones and "poison" designation is required on your product label.

Item 7D. STATEMENT OF PRACTICAL TREATMENT - Refer to the second chapter of the Registration Standard.

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear togther on the label under the heading "PRECAUTIONARY STATEMENT." It is preferred that they appear at the top or side of the back panel, preceding the directions for use, and that they be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - The following precautionary statement may be required on certain product labels containing this active ingredient. Refer to the registration standard to

determine if your product should contain the statement: "HAZARD TO HUMANS & DOMESTIC ANIMALS"

Item 8B. ENVIRONMENTAL HAZARD - Environmental hazard statements may be required on certain product labels containing this active ingredient. Refer to the registration standard to determine whether or not your product label should bear any such statement and the precise wording of the statement.

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).

ii. There is no flash back; and

iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the item "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

In Chapter 2 of the registration standard, the Agency has: (1) indicated certain formulations/uses to be restricted based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted based on data

already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data most of which has yet to be generated.

The product-specific data required by the Standard should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix V-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination and must be consistent with the terms of 40 CFR §162.10 and this guidance package with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the Standard should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

   a. Front panel statement of restricted use classification.

      i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement, "Restricted Use Pesticide" shall appear.

ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a

RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are not unrestricted from those that are RESTRICTED.

iii. You may register two separate products with identical formulations, one containing only unrestricted uses and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products begins only after the approved label is returned to you as follows:

a. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 120th day

after the date of acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling. For the purposes of the first phase of reregistration, supplemental labeling means:

(i) an adhesive sticker containing the restricted use statement specified in 40 CFR 162.10(j)(2) and also found in this section;

ii. a separate form containing the product name as it appears on the restricted use statement specified in 40 CFR §162.10(j)(2) and also found in this section, and

iii. the approved new label.

b. No product with a use classified for restricted use under this first phase of reregistration may be distributed or sold by retailers or other persons after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling.

c. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

d. In cases where a registrant chooses to delete product uses classified as restricted under the first phase of reregistration, no such product may be released for shipment by the registrant or producer after the 180th day after acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

e. No product with a use classified as restricted under this first phase of reregistration may be advertised without including the restricted use classification after the 120th day after the acceptance of the label submitted in conjunction with your application.

Brochures, technical pamphlets and similar material which are in final printed form on the date of acceptance of the

new label may be distributed only for 270 days from the date of acceptance.

Item 9C. MISUSE STATEMENT - The following statement is required on your label: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Appendix V-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. RE-ENTRY STATEMENT - If there is a reentry statement for your product, that statement will be set forth in the second chapter of the standard.

Item 10C. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 of the latest specific storage and disposal product labels.

Item 10D. DIRECTION FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person

likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-5. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

C. Special (Child Resistant) Labeling Requirements

As required in 40 CFR 162.16 (Appendix V-6), any pesticide that is released for shipment by the registrant after March 9, 1981 must be in special packaging if:

(1) its labeling permits residential use;

(2) it has not been classified for restricted use and

(3) it meets the toxicity criteria of 40 CFR 162.16(c)(2).

Additional information on child resistant packaging is being developed and will be mailed to you shortly.

VI. Instruction for Submission

All applications prepared in response to this Notice should be addressed as follows:

Product Manager
Phone No. (202)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each affected product for which continued registration is desired, you must:

A. Within 90 days from receipt of this package you must submit the "FIFRA" Section (3)(c)(2)(B) Summary Sheet (Appendix III-2) with appropriate attachments.

B. Within 6 months from receipt of this package you must submit:

1. "Application for Amended Pesticide Registration" (EPA Form 8570-11).

2. "Confidential Statement of Formula" (EPA Form 8570-4).

3. "Data Compensation Statement: Reregistration" (Appendix II-1).

4. Product Specific Data Report (Appendix II-2).

5. Two copies of any required product-specific data.

6. Two copies of draft labeling, including the label and associated brochures. If the current accepted labeling conforms to the requirements of the guidance package and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either type-written text on 8 1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8 1/2 x 11 inch files. The draft label must indicate the intended

colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

7. A progress report on the development of generic mid-term and long-term data.

C. Within 24 months from the receipt of this package you must submit:

1. All required generic mid-term data (Table A).

2. A progress report on the development of generic long-term data (Table A).

D. Within 42 months from the receipt of this package you must submit the generic long-term data as committed (Table A).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

VII. STATEMENT ON AGENCY POSITION REGARDING COURT SUITS INVOLVING FIFRA SECTION 3(c)(1)(D)

Several companies have sued EPA in an attempt to block implementation of FIFRA Section 3(c)(1)(D), which allows EPA to consider one firm's data in support of reregistration of another firm's product. EPA considers all available generic data in preparing a registration standard. If the companies are successful in the litigation, they could then use the reregistration process as a means of forcing competitors off the market. EPA does not intend to allow the reregistration requirement to be distorted in this fashion. If your application for reregistration would be affected by this litigation, you will receive further instructions from EPA before the time your application must be submitted to EPA.

Appendix II-1

DATA COMPENSATION STATEMENT: REREGISTRATION

EPA Reg. No.:_____

Product Name:_____

Applicant's Name & Address:_____

_____

_____

Date of application for reregistration: _____

Registration Standard for products containing:_____

Date Reregistration Standard Issued:_____

Date Reregistration Guidance Package Issued:_____

In connection with applicant's application for reregistration under the Registration Standard and Guidance Package identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA appoves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Registration Standard and Guidance Package identified above, were found relevant to EPA's evaluation of the registrability of applicant's product (taking into account the product's composition and formulation category, and the uses its label will permit); and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application.

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Package identified above.

Dated: _____

Name of registrant's
authorized representative: _____
(signature)

_____
(typed)

EPA Registration No. _____

Reg.Std for _____
Date Reg. Std. Issued: _____
Guidance Package Date: _____

Registration Guideline No.	Name of Test	Test not required for my Product Listed Above (check below)	I am complying with Data Requirements By: Citing MR ID #	I am complying with Data Requirements By: Submitting Data (attached) (check below)	(For EPA Use Only) Accession Numbers Assigned
163.61-3	Product identitity and disclosure ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredient				
-6	Declaration and certification of ingredient limits				
7	Product analytical methods and data				
163.61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting Point				
-8(4)	Solubility				
-8(5)	Stability				
-8(6)	Octanol/water partition coefficient				
-8(7)	Physical State				
-8(8)	Density or specific gravity				
-8(9)	Boiling Point				
-8(10)	Vapor pressure				
-8(11)	pH				
-8(12)	Storage stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
-8(17)	Viscosity				
-8(18)	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
163.71-5(1))	Cage or pen field test				
-5(2)	Full-scale field test				
163.72-1	Fish acute LC_{50}--rainbow trout and bluegill				
-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short term simulated field test				
-6(a)(2)	Long term simulated field test				
163.81-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name: _____

As an authorized representative of the registrant of the product identified above, I hereby certify that:

(1) I have read and am familiar with the terms of a Notice in a Guidance Package from EPA dated _____ concerning a requirement for submission of generic data on the active ingredient _____ under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product and it contains the active ingredient solely as the result of the incorporation into the product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate confidential formula statement for the above-identified product, is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient in my firms's product. My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertaking made in this statement, my firm's product's registration may be suspended in accordance with FIFRA Section 3(c)(2)(B).

Dated: _____

Registrant's Authorized Representative: _____
(Signature)

_____
(Typed)

FIFRA § 3(C)(2)(B) SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Applicant's Name: _____
Registration Standard for Products Containing: _____
Date Registration Standard Issued: _____
Date Guidance Package Issued: _____

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Package, I am responding in the following manner:

1. ☐ Attached is a completed "Generic Data Exemption Statement."

2. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

3. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

4. ☐ I enclose a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants For Development Of Data" with respect to the following data requirements:

5. ☐ I request that you amend my registration by deleting the following uses:

6. ☐ I request voluntary cancellation of the registration of this product.

Dated: _____

Registrant's Authorized Representative:

_____
(signature)

_____
(typed)

STATEMENT OF WILLINGNESS TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a guidance package dated _____ to submit data concerning the active ingredient _____:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

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

Firm	Date of offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B).

Dated: _____ _____
(Signature)

_____
(Typed)

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

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(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of

the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.

Hazard indicators	Toxicity categories			
	I	II	III	IV
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	8	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects.
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or, for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

(A) Pressurized Containers

Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(B) Nonpressurized Containers

Flash point	Required text
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv)).

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for

use(s) classified general shall be labeled with the exact word "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5736, Feb. 9, 1978]

TABLE D

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED [Refer to the sample labels following]

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product Name	All Products	Front panel	Center front panel	
2	Company Name and Address	All Products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for***" "Distributed by ***", etc.
3	Net Contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Est. No.	All Products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All Products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statement	All Products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front Panel Precautionary Statements	All Products	Front Panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child Hazard Warning)	All Products	Front Panel	Above signal word	Note type size requirements.

TABLE E

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal Word	All Products	Front panel	Immediately below Child Hazard Warning	Note type size requirements
7C	Skull & Crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral Statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	SIDE/BACK PANEL PRECAUTIONARY STATEMENTS	All products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings in 8a, 8b, and 8c; Preferably blocked
8A	Hazards to Humans and Domestic Animals	All Products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word
8B	Environmental Hazards	All Products	None	Same as above	Environmental hazards include bee caution where applicable
8C	Physical or Chemical Hazards	All pressurized products; others with flash points under 150 F	None	Same as above	

TABLE F

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
9A	Restricted Block	ALL RESTRICTED products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words, "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse Statement	All products	Immediately following Statement of Classification or head of Directions for Use		
10A	Re-entry Statement	All cholinesterase inhibitors	In the Directions for Use	Immediately after Misuse Statement	
10C	Storage and Disposal Block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type size as Child Hazard Warning
10D U.S.	Directions for Use	All products	None	None	May be in metric units as well as U.S. units.

8

8A PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

8B ENVIRONMENTAL HAZARDS

8C PHYSICAL OR CHEMICAL
HAZARDS

RESTRICTED USE PESTICIDE

9A

- For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

PRODUCT NAME

1

ACTIVE INGREDIENT: _____ %
INERT INGREDIENTS _____ %

6A

TOTAL: 100.00 %

7

6B THIS PRODUCT CONTAINS LBS OF PER GALLON

10A RE-ENTRY STATEMENT
(If applicable)

KEEP OUT OF REACH OF CHILDREN

1A

1B DANGER—POISON

1C

10C STORAGE AND DISPOSAL

STORAGE

DISPOSAL

STATEMENT OF PRACTICAL TREATMENT

1D

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

1E

DIRECTIONS FOR USE

9C It is a violation of Federal law to use this product in a manner inconsistent with its labeling

10D CROP:

MFG BY
TOWN, STATE
5 ESTABLISHMENT NO
EPA REGISTRATION NO

2
4

NET CONTENTS

3

CROP:

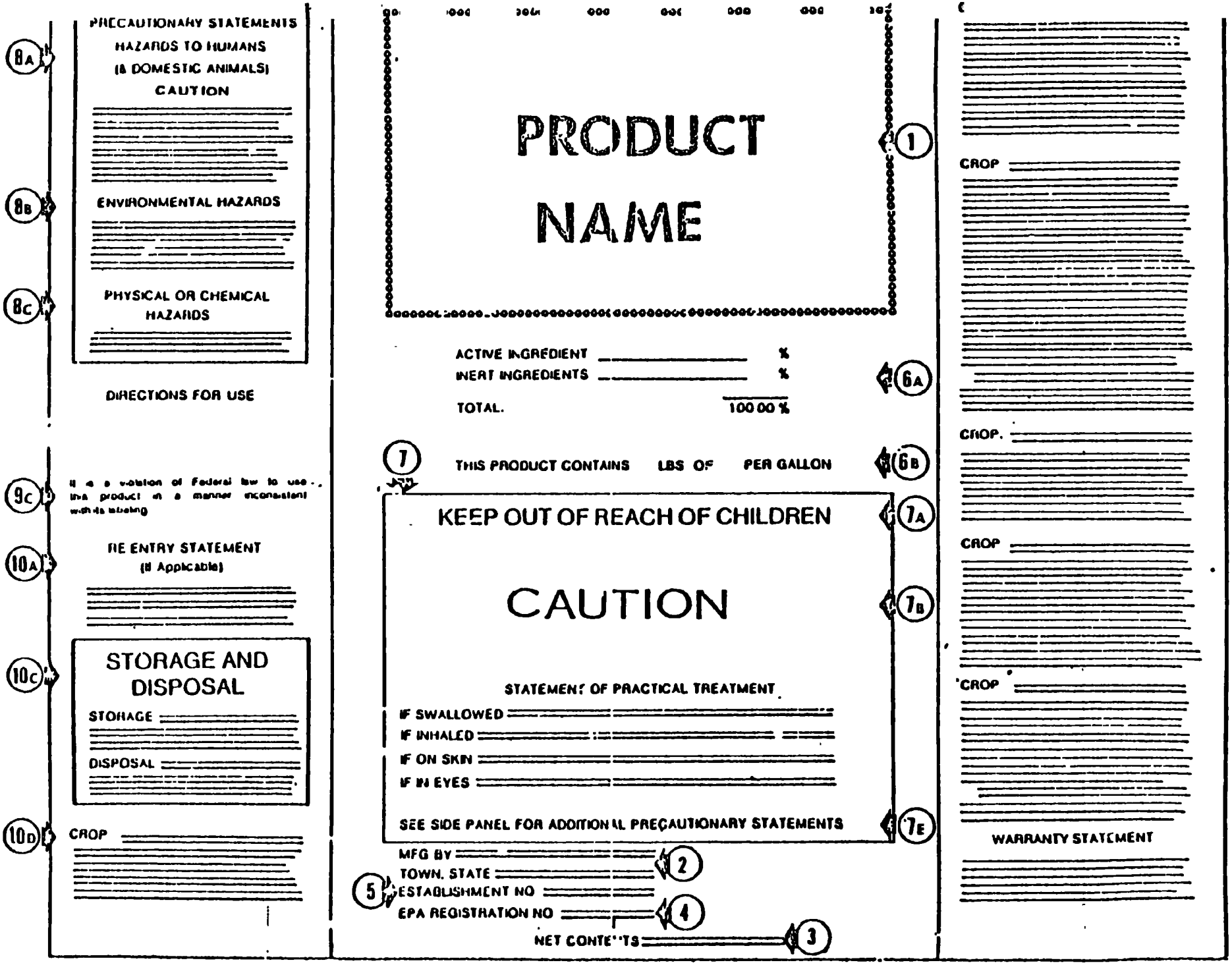
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8A
ENVIRONMENTAL HAZARDS
8B
PHYSICAL OR CHEMICAL
HAZARDS
8C
DIRECTIONS FOR USE
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
10A
RE ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10D
CROP
PRODUCT
NAME
1
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL. 100.00 %
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP.
CROP
CROP
WARRANTY STATEMENT

Physical - Chemical Hazards

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flash points at or below 20°F; or if there is a flashback at any valve opening	Extremely Flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20° and not over over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F	Flammable. Keep away away from heat and open flame
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Above 150°F	None Required

162.11

(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i)-(iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 2,000 mg/kg;

(B) Has an inhalation LC_{50} greater than 2 mg/liter;

(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;

(D) Causes no more than moderate skin irritation within 72 hours;

(E) Has an acute oral LD_{50} greater than 1.5 g/kg for the formulation as diluted for use; and

(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 200 mg/kg;

(B) Has an acute dermal LD_{50} greater than 16 g/kg for the formulation as diluted for use as a mist or spray;

(C) Has an inhalation LD_{50} greater than 0.2 mg/liter;

(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days;

(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and

(F) Causes under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their their metabolite(s), or degradation product(s).

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅛ the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the

average daily intake of such representative species, at levels less than ⅕ the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $\frac{1}{10}$ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.

(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has submitted the toxicity data on the product use(s) required in paragraph (c)(1) of this section, the existing Toxicity Category determinations shall be used to establish whether the pesticide use(s) is a candidate for general or restricted use classification. Except as provided in paragraph (c)(4) of this section, specific use(s) of a product shall be classified for general use if the applicable criteria set forth in paragraph (c)(2) (i)–(iii) of this section are met. Otherwise, the product use shall be classified for restricted use unless a review of the labeling pursuant to paragraph (3) of this paragraph (c) indicates that the use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I or II; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species at levels less than ⅕

the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $\frac{1}{10}$ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from the application, such as through volatilization, drift, leaching or lateral movement in soil.

(3) *Adequacy of label and labeling.* The directions, warnings, and cautions for any product use(s) not meeting the criteria set forth in paragraphs (c) (1) and (2) of this section shall be further evaluated according to the criteria set forth below to determine the adequacy of the label or labeling to prevent unreasonable adverse effects on man or the environment. If these criteria are met, the labeling for the affected uses will be considered adequate to prevent unreasonable adverse effects on the environment without further regulatory restrictions, and the affected uses will be classified for general use. The criteria for evaluating labeling adequacy are as follows:

(i) To follow label directions, the user of a pesticide product would not have to perform complex operations or procedures requiring specialized training and/or experience;

(ii) Failure to follow the use directions in any minor way would result in minor or no discernible adverse effects;

(iii) Widespread and commonly recognized practices of use would not nullify label directions relative to prevention of unreasonable adverse effects on man and the environment;

(iv) The directions do not call for specialized apparatus, protective equipment or material unless they would be expected to be available to the general public;

(v) Following directions for use would result in only minor or no discernible adverse effects of a delayed or indirect nature, such as through bioaccumulation, persistence, or pesticide movement from the original application site, on nontarget organisms.

(4) *Other Hazards.* Any product use(s) which meets the general use criteria of paragraph (c) (1), (2), or (3) of this section shall nonetheless be classified for restricted use if the Agency determines that based on human toxicological data (including epidemiological studies), use history, accident data, monitoring data, or such other evidence as the Administrator identifies the product use(s) may pose a serious hazard to man or the environment which can reasonably be prevented by classification for restricted use.

(5) *Other regulatory restrictions.* Any product use(s) classified for restricted use under the provisions above may be limited to use by or under the direct supervision of a certified applicator. The Administrator may additionally or alternatively impose other restrictions by regulation. Such regulatory restrictions may include, but are not limited to, seasonal or regional limitations, limitation of use to approved pest management programs, or a requirement for monitoring of residue levels after use, and may be utilized to reduce human health and environmental hazards associated with persistent, bioaccumulative, or mobile, or highly toxic pesticides. Any such regulation shall be reviewable in the appropriate Court of Appeals upon petition of a person adversely affected filed within 60 days of the publication of such regulation in final form.

STORAGE AND DISPOSAL STATEMENTS

Storage and disposal statements are based upon the type of container used, and upon the pesticide which is or was in the container.

1. All products registered for home and/or garden use are exempted from requirements for other statements if they bear the following:

DISPOSAL

DO NOT REUSE EMPTY CONTAINER.
WRAP CONTAINER AND PUT IN TRASH COLLECTION.

CONTAINER: METAL

SIZE: LESS THAN 30 GALLONS

CHEMICAL: ORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. OPEN DUMPING IS PROHIBITED.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF IN A LANDFILL APPROVED FOR PESTICIDES OR BURIED IN SAFE PLACE AWAY FROM WATER SUPPLIES.

3. CONTAINER DISPOSAL

TRIPLE RINSE (OR EQUIVALENT) AND

OFFER FOR RECYCLING, RECONDITIONING, OR DISPOSAL IN APPROVED LANDFILL OR BURY IN A SAFE PLACE.

4. GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

Note: AT MANUFACTURER'S OPTION, HE MAY INCLUDE A STATEMENT, "RETURN TO MANUFACTURER"

CONTAINER: FIBRE DRUMS

SIZE: ALL SIZES

CHEMICAL: ORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

-DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

-OPEN DUMPING IS PROHIBITED.

-DO NOT REUSE EMPTY CONTAINER.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF IN A LANDFILL APPROVED FOR PESTICIDES OR BURIED IN SAFE PLACE AWAY FROM WATER SUPPLIES.

3. CONTAINER DISPOSAL

DISPOSE OF IN AN INCINERATOR OR LANDFILL APPROVED FOR PESTICIDE CONTAINERS, OR BURY IN A SAFE PLACE.

4. GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES SUCH AS LIMITED OPEN BURNING.

Note: AT MANUFACTURER'S OPTION, HE MAY INCLUDE A STATEMENT: "RETURN TO MANUFACTURER"

CONTAINER: GLASS

SIZE: ALL SIZES

CHEMICAL: ORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. OPEN DUMPING IS PROHIBITED. DO NOT REUSE EMPTY CONTAINER.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF IN A LANDFILL APPROVED FOR PESTICIDES OR BURIED IN SAFE PLACE AWAY FROM WATER SUPPLIES.

3. CONTAINER DISPOSAL

TRIPLE RINSE (OR EQUIVALENT) AND DISPOSE OF IN AN APPROVED LANDFILL OR BURY IN A SAFE PLACE.

4. GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES SUCH AS LIMITED OPEN BURNING.

CONTAINER: METAL

SIZE: LESS THAN 30 GALLONS

CHEMICAL: METALLO-ORGANIC & INORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. OPEN DUMPING IS PROHIBITED.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF ACCORDING TO PROCEDURES APPROVED BY FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES.

3. CONTAINER DISPOSAL

TRIPLE RINSE (OR EQUIVALENT) AND DISPOSE OF IN AN APPROVED LANDFILL OR BURY IN A SAFE PLACE.

4. GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

Note: AT MANUFACTURER'S OPTION, HE MAY INCLUDE A STATEMENT: "RETURN TO MANUFACTURER."

CONTAINER: FIBRE DRUMS

SIZE: ALL SIZES

CHEMICAL: METALLO-ORGANIC & INORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

-DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

-OPEN DUMPING IS PROHIBITED.

-DO NOT REUSE EMPTY CONTAINER.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF ACCORDING TO PROCEDURES APPROVED BY FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES.

3. CONTAINER DISPOSAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

Note: AT MANUFACTURER'S OPTION, HE MAY INCLUDE A STATEMENT: "RETURN TO MANUFACTURER."

CONTAINER: GLASS

SIZE: ALL SIZES

CHEMICAL: METALLO-ORGANIC & INORGANIC

STORAGE AND DISPOSAL

1. PROHIBITIONS

-DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

-OPEN DUMPING IS PROHIBITED.

-DO NOT REUSE EMPTY CONTAINER.

2. PESTICIDE DISPOSAL

PESTICIDE, SPRAY, MIXTURE, OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF ACCORDING TO PROCEDURES APPROVED BY FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES.

3. CONTAINER DISPOSAL

TRIPLE RINSE (OR EQUILVALENT) AND DISPOSE OF IN AN APPROVED LANDFILL OR BURY IN A SAFE PLACE.

4. GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

§ 162.16 Pesticides requiring special packaging.

(a) *General.* This section implements Section 25(c)(3) of the Act, which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act.

(b) *Definitions.* Terms used in this section shall have the same meaning set forth in the Act and in § 162.3. In addition, as used in this section:

(1) The term "package" means the immediate container or wrapping in which any pesticide is contained for consumption, use or storage. "Package" does not include:

(i) Any shipping container or wrapping used solely for the transportation of any pesticide in bulk or in quantity to manufacturers, packers or processors, or to wholesale or retail distributors thereof; or

(ii) Any shipping container or other wrapping used by retailers to ship or deliver any pesticide to consumers unless it is the only such container or wrapping.

(2) The term "residential application" means application of a pesticide (other than application by a commercial applicator) directly to humans or pets or application of a pesticide in, on or around all structures, vehicles or areas associated with the household or homelife or non-commercial areas where children spend time, including, but not limited to:

(i) Gardens, non-commercial greenhouses, yards, patios, houses, pleasure marine craft, mobile homes, campers and recreational vehicles, non-commercial campsites, home swimming pools and kennels;

(ii) Articles, objects, devices or surfaces handled or contacted by humans or pets in all structures, vehicles or areas listed above; and

(iii) Educational, lounging and recreational areas of preschools, nurseries and day camps.

(3) The term "special packaging" means packaging that is designed and constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

(4) The term "unit package" means a package that is labeled with directions to use the contents in a single application or which consists of individually packaged dosage units.

(c) *Pesticides requiring special packaging*—(1) *General.* Any pesticide product that is released for shipment after insert date 2 years from date of publication shall be specially packaged if (i) its labeling allows residential use, (ii) it has not been classified for restricted use and (iii) it meets the toxicity criteria in paragraph (c)(2) of this section. Special packaging may be required on a case-by-case basis for pesticide products which are classified for restricted use, if the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

(2) *Criteria for special packaging.* Special packaging is required for a pesticide product approved for residential application if the tests conducted in accordance with Part 162 indicate that the pesticide formulation:

(i) Has an acute dermal LD_{50} of 2000 mg/kg or less;

(ii) Has an inhalation LC_{50} of 2 mg/liter or less;

(iii) Is corrosive to the eye (causes irreversible destruction of ocular

tissue) or causes corneal involvement or irritation persisting for 21 days or more;

(iv) Is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe skin irritation (severe erythema or edema) at 72 hours;

(v) Has an acute oral LD_{50} of 1.5 g/kg or less; or

(vi) Has such characteristics that, based upon human toxicological data, use history, accident data or such other evidence as is available, the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

(3) *Exemptions.* Upon the request of a registrant or applicant the Administrator may on a case-by-case basis, grant an exemption, based on supporting data accompanying the request, for products for which special packaging is not technically feasible or for those pesticides for which the hazards indicated by the toxicity criteria in paragraph (c)(2) of this section are not indicative of hazard to man. Any such decision shall be published in the FEDERAL REGISTER and shall be applicable to any product with identical or substantially similar composition and intended uses.

(4) *Unit packaging.* Pesticides requiring special packaging and which use unit packaging shall either package each unit package in a special package or use special packaging for the retail container which contains unit packages. Special packaging will not be required for both the outer container and the unit packages unless, on a case-by-case basis, further information shows that it is necessary for hazard reduction.

(d) *Standards for special packaging*—(1) *General requirements.* (i) The special packaging must continue to function with the effectiveness specifications set forth in paragraph (d)(2) of this section when in actual use as a pesticide container. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging and that the packaging will not be detrimental to the integrity of the product during storage and use.

(ii) The special packaging must continue to function with the effectiveness specified in paragraph (d)(2) of this section for the reasonably expected lifetime of the package, taking into account the number of times the package is customarily opened and closed. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other relevant factors.

(2) *Effectiveness specifications.* The special packaging, when tested by the method referred to in paragraph (d)(3) of this section, shall meet the following specifications:

(i) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening the package. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(ii) Adult-use effectiveness of not less than 90 percent without a demonstration.

(3) *Effectiveness testing procedures.* Standards for special packaging shall be evaulated for each size of a design used pursuant to the Consumer Product Safety Commission (CPSC) protocols specified in 16 CFR 1700.20(a), (b), (c) and (d).

(e) *Submission.* The registrant of a registered pesticide which requires special packaging shall submit an application for amended registration under § 162.6(b)(3). The application shall include a certification by the registrant that the package meets the standards of § 162.16(d). An applicant for a new registration shall submit a certification statement that the package meets the standards of § 162.16(d) with the application for registration.

(f) *Record keeping.* The applicant or registrant of a pesticide for which special packaging is required shall retain the records described in paragraphs (f)(1), (2), and (3) of this section for as long as the registration is valid. These records shall be available, upon re-

quest, for inspection and copying purposes or for submission to EPA.

(1) A full description of the package including:

(i) A full description of the container including:

(A) Its dimensions, and

(B) Its compositions; and

(ii) A full description of the closure or special package, if appropriate, including:

(A) The name of its manufacturer,

(B) The manufacturer's designation (title) for the special packaging closure or the physical working of the special packaging mechanism, and

(C) The explicit directions for proper use of the closure or special packaging and the placement of these directions on the package;

(2) A complete copy of the data resulting from the tests conducted in accordance with § 162.16(d); and

(3) Data demonstrating the compatibility of the pesticide formulation with the entire package to determine that the chemical and physical characteristic of the substances will not interfere with the safety and efficacy of the pesticide and the functioning of the special package.

(g) *Enforcement.* Failure to comply with this rule by its implementation date renders a pesticide misbranded under Section 2(q)(1)(B) of FIFRA, and is a violation of Section 12(a)(1)(E) of FIFRA. Registrants who violate these sections will be subject to civil and criminal penalties under Section 14 of FIFRA.

(Secs. 3 and 25(c)(3), Federal Insecticide, Fungicide, and Rodenticide Act, as amended (Pub. L. 92-516, 86 Stat. 973; Pub. L. 94-140, 89 Stat. 755; 7 U.S.C. 136 et seq.))

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