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United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(H-7508W)

EPA

Reregistration Eligibility Document (RED)

Ethylene

REREGISTRATION ELIGIBILITY DOCUMENT

ETHYLENE

LIST C

CASE 3071

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

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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EXECUTIVE SUMMARY

This reregistration eligibility document (RED) is the United States Environmental Protection Agency ("EPA" or the "Agency") regulatory position on the continued registration of the pesticide ethylene and its uses. Products containing ethylene are currently registered as plant growth regulators and herbicides. Commercially, ethylene is used as a ripening agent for fruits and vegetables, a curing agent for tobacco, and to promote flower production in pineapples. It is also used to control witchweed in corn, cotton, peanuts and soybeans. The first registered product containing ethylene was registered in December, 1971.

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

Before reregistering each product, the Agency is requiring confidential statements of formula and revised product labeling to be submitted within eight months from the issuance of this document. After reviewing these confidential statements of formula and revised labels, the Agency will determine whether or not the conditions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(5) have been met, that is, whether confidential statements of formula and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met, the Agency will reregister the products. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

Chemical Name: ethylene

CAS Registry Number: 74-85-1

Office of Pesticide Programs Chemical Code: 41901

Empirical Formula: $C_2 H_4$

B. Use Profile

The following is information on the current registered uses and application methods. A detailed table of all uses of ethylene is in Appendix A.

Type of Pesticide: herbicide, plant growth regulator (to accelerate the ripening of harvested fruits and vegetables, curing agent for tobacco)

Target pest (herbicide): witchweed

Use Sites:
Terrestrial Food - fruits, vegetables
Indoor Food - fruits, vegetables
Indoor Nonfood - tobacco
Terrestrial food/feed - (herbicide) - corn, cotton peanuts, soybeans

Formulation Types

Technical Grade: 99.9%
Formulations: 6.2% - 99.5%

Method of Application:

Types of Treatment: ground soil injection (herbicide use), stored commodity fumigation, foliar spray

Equipment: gas generator, soil injector, pressure sprayer

Timing: postharvest (for stored commodities), May thru July (for soil injection - herbicide use)

Rates of Application: See Appendix A

C. Regulatory History

As stated in the Executive Summary the first product containing ethylene was registered in December, 1971. The currently registered products (8) are used as plant growth regulators and herbicides in the sites identified in Section II.B above.

On May 18, 1990, the Agency designated ethylene as a biochemical pesticide based on the following scientific reasons: 1) it is a naturally occurring compound and 2) it has a nontoxic mode of action in target pests/plants.

III. SCIENCE ASSESSMENT OF ETHYLENE

A. Product Chemistry Assessment

Ethylene is a naturally occurring plant growth regulator with a molecular weight of 28.05. It is a colorless, flammable gas. Burns with a luminous flame. One volume of ethylene gas dissolves in about 4 volumes of water at 0°C, in about 9 volumes of water at 25°C, in 0.5 volumes of alcohol at 25°C, and in about 0.05 volume of ether at 15.5°C. It is soluble in acetone and benzene.[2]

[2] The Merck Index. Eleventh Edition, 1989. p. 597.

EPA has reviewed the scientific data base for ethylene primarily relying on information from the published literature. These sources are cited in Appendix B and C.

B. Human Health Assessment

1. Toxicology Data

The Agency believes there are sufficient data from the published literature to make a hazard assessment of the uses of ethylene. Therefore, the Agency is using published sources of information, cited below, rather than requiring new studies from registrants.

Ethylene is a gas and therefore, the only relevant route of exposure of toxicological concern is the pulmonary route. Widespread human exposure from the clinical use of ethylene as an anesthetic in the absence of any reports of significant toxicity are sufficient to allow the Agency to conclude that ethylene will be nontoxic to humans under the conditions of use as a plant regulator or in a witchweed control program.

Ethylene has been used as a clinical anesthetic since 1923. Anesthesia is complete within 20-30 minutes with 90% in oxygen. The percentage of ethylene may be reduced toward 80% in prolonged anesthesia. If the concentration is beyond 90% in animals, death results from respiratory failure. The lethal concentration for mice in air is 950,000 ppm ethylene.[3]

During established anesthesia, respiration is practically normal...and the pulse scarcely changed, excitability of the medullary centers is not lowered, the asphyxia is slight and does not proceed to cyanosis, sweating and salivation are slight or absent, temperature fall is relatively slight, renal efficiency... is not impaired, pulmonary irritation... appears to be absent, in obstetrical use, it does not materially reduce the uterine contractions, and permits prompt respiration to the delivered child, gastric movements are only slightly depressed, ... movements of the small and large intestines are stimulated.[4]

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[3] The Merck Index. Eighth edition, 1968.

[4] T. Sollmann, W.B. Sauders Company. Pharmacology and it's Applications to Therapeutics and Toxicology, 8th edition, 1964,

Ethylene is more advantageous than ether as an anesthetic because of safer induction and more rapid recovery. It is also more advantageous than nitrous oxide because of the practical absence of asphyxia.

The maximum exposure rate to ethylene under the current uses is 1000 ppm in the post-harvest treatment of stored commodities. By contrast, natural internal levels of ethylene in pineapples may reach as high as 1100 ppm and in apples as high as 2500 ppm.

No long-term problems have been attributed directly to the gas. The gas does not have local toxic effects.[5]

2. Dietary Exposure

Ethylene is exempt from the requirement of tolerance (40 CFR 180.1016) for residues when: a) used as a plant regulator on fruit and vegetable crops; or b) injected into the soil to cause premature germination of witchweed in fields of a number of crops as part of the U.S. Department of Agriculture witchweed control program. Therefore no residue data are required because of the lack of concern for mammalian toxicity.

3. Occupational and Residential Exposure

The Agency has waived these data requirements for the following reasons: a) low mammalian toxicity concerns and b) the high volatility of ethylene minimizes the post-application exposure to foliage, soil, dermal and inhalation. However, there is some hazard of dermal and ocular frost burns and of flammability posed by the compressed gas. Therefore, protective clothing, rubber gloves and goggles are required while handling cylinders or any application equipment under pressure.

4. Human Risk Assessment

With the exception of the physical/chemical hazards noted above, the potential risks to humans from occupational exposure are considered negligible due to: a) low toxicity concerns, b) ethylene's widespread use as an anesthetic and c) minimal dermal exposure.

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[5] J. Doull, C.D. Klaassen, M.O. Amdur. The Basic Science of Poisons, 2nd. Edition, 1980. Macmillan, New York.

C. Environmental Assessment

1. Ecological Effects Data

Ethylene is a naturally occurring gas that is produced in plants and acts on nontarget pest(s)/plants(s) through a nontoxic mode of action. Because it is naturally occurring and it has a nontoxic mode of action, ethylene has been classified as a biochemical. Ecotoxicity data are usually required for indoor use of biochemicals depending upon use pattern, production volume and other factors such as volatility. However upon these factors and its classification as a biochemical, no ecological effects studies are required for ethylene for indoor uses.

Data requirements for the outdoor uses have been waived because of its volatile nature, the method of application in the case of soil injection and its relatively low rate of application in the case of sprays to pineapples (2.5 lb/acre). The Agency believes that for the above reasons there will be minimal exposure to aquatic and terrestrial organisms for the outdoor uses of ethylene.

2. Environmental Fate Data

Environmental fate studies are not required for biochemical pesticides unless adverse effects on fish and wildlife observed as a result of acute testing (Tier I) for ecological effects. As stated above, the ecotoxicity studies have been waived for the outdoor uses of ethylene and therefore no environmental fate studies are required.

3. Environmental Risk Assessment

The Agency believes for the reasons stated above that the environmental risks for ethylene products are minimal.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR ETHYLENE

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA requires the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has waived all generic (i.e., active ingredient specific) data requirements except for technical chemistry data and additionally has relied on public literature for mammalian toxicology. The Agency has completed its review

of this information data and other factors and considerations, and has determined this information is sufficient to support reregistration of all products containing ethylene for all uses. Appendix B identifies the data that the Agency reviewed for the determination of reregistration eligibility for ethylene.

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

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

B. Labeling Requirements for Manufacturing-Use Product(s) of ethylene

1. Under the heading "Directions for Use" add the following statement.

"Only For Formulation Into An_____, [fill blank with Insecticide, Herbicide, or the applicable term(s) which describe the type of pesticidal use(s)] For (1) The Following Use(s): _____ _____; or (2) Uses For Which US EPA Has Accepted The Required Data And/Or Citations of Data That The Formulator Has Submitted In Support of Registration; and (3) Uses For Experimental Purposes That Are In Compliance With US EPA Requirements."

2. The signal word is "DANGER".

3. The Precautionary Statements must read:

"Liquefied or pressurized gas can cause frost burns. Do not get in eyes or on skin. Wear long-sleeved shirt, long pants, boots, goggles and chemical-resistant gloves while handling cylinders or any application equipment under pressure. Harmful if inhaled. Avoid breathing vapors. Do not enter unventilated treatment areas unless wearing a respirator approved by NIOSH/ MSHA for this use."

4. The Statements of Practical Treatment (First Aid) must read:
"IF IN EYES: Flush with plenty of water. Call a physician."

"IF ON SKIN: Wash with plenty of soap and water. Get medical attention."

"IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

5. The Physical or Chemical Hazards statement must read:
[For the technical grade product]
"Contents under pressure. Do not store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees Fahrenheit may cause bursting."

V. ACTIONS REQUIRED BY REGISTRANTS

A. Determination of Eligibility

Based on consideration of data and information submitted for the active ingredient, ethylene and the registered use patterns, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA requires that the Agency obtain any needed product-specific data regarding the pesticide following a determination of eligibility. However, the Agency is not requiring any product specific data, it will review the confidential statements of formula and labels of these products to determine whether they may be reregistered.

B. Product Specific Data Requirements

The Agency is primarily relying on information from published literature to meet the data requirements for the technical material. Because the end-use products are similar in composition to the technical material, the Agency is not requiring any further product specific for the products containing ethylene as an active ingredient. Additionally, the labeling requirements prescribed in Section V.C. are sufficient to address the only product that does not have a similar percent amount of active ingredient.

C. Labeling Requirements for End-Use Products

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in PR Notice 91-2 (Appendix D) and the Product Reregistration Handbook (Appendix E) with respect to labels and

labeling.

2. The labeling must include the following statement for the foliar spray (pineapple use).

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

3. The signal word is "DANGER".

4. The Precautionary Statements must read:

"Liquefied or pressurized gas can cause frost burns. Do not get in eyes or on skin. Wear long-sleeved shirt, long pants, boots, goggles and chemical-resistant gloves while handling cylinders or any application equipment under pressure. Harmful if inhaled. Avoid breathing vapors. Do not enter unventilated treatment areas unless wearing a respirator approved by NIOSH/MSHA for this use."

5. The Statements of Practical Treatment (First Aid) must read:

"IF IN EYES: Flush with plenty of water. Call a physician."

"IF ON SKIN: Wash with plenty of soap and water. Get medical attention."

"IF INHALED: Remove victim to fresh air. If not breathing, get artificial respiration, preferably mouth-to-mouth. Get medical attention."

6. The Physical or Chemical Hazards Statement must read:

"Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees Fahrenheit may cause bursting."

APPENDIX A

ETHYLENE USE PATTERNS SUBJECT TO REREGISTRATION

APPENDIX A - Case 3071, [Ethylene] Chemical 041901 [Ethylene]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
FOOD/FEED USES										
BANANA USE GROUP(S): Indoor Food										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm/1 cu.ft	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	0.2664 cu.ft/hr/1K cu.ft	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
				not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
CITRUS FRUITS USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	5 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
CORN (UNSPECIFIED) USE GROUP(S): TERRESTRIAL FOOD + FEED CROP										
Soil injection treatment, May, June, July, soil injection equipment	PrGs	na	1.5 lb AI/A	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
COTTON (UNSPECIFIED) USE GROUP(S): TERRESTRIAL FOOD + FEED CROP										
Soil injection treatment, May, June, July, soil injection equipment	PrGs	na	1.5 lb AI/A	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
GRAPEFRUIT USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	5 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.

APPENDIX A - Case 3071, [Ethylene] Chemical 041901 [Ethylene]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls. @ Max. Rate	Min. Interval Between Appls. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations and Restrictions
LEMON USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
MELONS USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
MELONS, HONEYDEW USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
ORANGE USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	5 ppm	not spec.	not spec.	.5	not spec.	not spec.	not spec.	not spec.
PAPAYAS USE GROUP(S): INDOOR FOOD										
PEANUTS (UNSPECIFIED) USE GROUP(S): TERRESTRIAL FOOD + FEED CROP										
Soil injection treatment, May, June, July, soil injection equipment	PrGs	na	1.5 lb AI/A	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
PEAR USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	.5	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
PERSIMMON USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.

APPENDIX A - Case 3071, [Ethylene] Chemical 041901 [Ethylene]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls	Max. # Appls @ Max. Rate	Min. Interval Between Appls @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations (See Abbreviations)
PINEAPPLE USE GROUP(S): TERRESTRIAL FOOD + FEED CROP, INDOOR FOOD										
High volume spray (dilute), Foliar, pressure sprayer	PrGs	na	2.5 lb AI/A	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
SOYBEANS (UNSPECIFIED) USE GROUP(S): TERRESTRIAL FOOD + FEED CROP										
Soil injection treatment, May, June, July, soil injection equipment	PrGs	na	1.5 lb AI/A	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
TANGERINES USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	5 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
TOMATO USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	150 ppm	not spec.	not spec.	.25	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	3.33 cu.ft/hr/1K cu.ft	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	200 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm/1 cu.ft	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	1000 ppm	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
WALNUT (ENGLISH/BLACK) USE GROUP(S): INDOOR FOOD										
Stored commodity fumigation, Postharvest, cylinder	PrGs	not spec.	1000 ppm	not spec.	not spec.	.5	not spec.	not spec.	not spec.	not spec.

APPENDIX A - Case 3071, [Ethylene] Chemical 041901 [Ethylene]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Appls.	Max. # Appls @ Max. Rate	Min. Interval Between Appls @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations also see Abbreviations
								Allowed	Disallowed	
NON-FOOD/NON-FEED USES										
TOBACCO/CIGAR/CIGAR WRAPPING USE GROUP(S): INDOOR NON-FOOD (SEE ALSO ISSUE)										
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	120 ppm/1K cu.ft	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	300 ppm/2.5 K cu.ft.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.	not spec.
Stored commodity fumigation, Postharvest, cylinder	PrGs	na	300 ppm	not spec.	not spec.	not spec.	not spec.	not spec	not spec.	not spec.

Abbreviations used

Header: not spec. = not specified;
Form: PrGs = Pressurized Gas;
Rate: na = not applicable; AI = Active Ingredient; A = Acre; ppm = parts per million;
Other: Minimum application rate is not in data base at this time.

APPENDIX B

Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the active ingredient covered by this Reregistration Eligibility Document. This appendix contains generic data requirements that apply to the pesticide (active ingredient) in all products, including data requirements for which a "typical formulation" is the test substance.

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

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

2. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of ethylene

Guideline Citation	Title of study	Citation
§158.690 Product Chemistry		
151-10	Product Identity	(1)
151-11	Manufacturing Process	(1)
151-12	Discussion of Formation	(1)
151-13	Analysis of samples	41600901
151-15	Certification of limits	(1)
151-16	Analytical Method	(1)
151-17(a)	Color	(1)
151-17(b)	Physical State	(1)
151-17(c)	Odor	(1)
151-17(d)	Melting Point	(1)
151-17(e)	Boiling Point	(1)
151-17(f)	Density	(1)
151-17(g)	Solubility	(1)
151-17(h)	Vapor Pressure	waived
151-17(i)	pH	waived
151-17(j)	Stability	(1)
151-17(k)	Flammability	(1)
151-17(p)	Octanol/water partition	(1)

(1) for all requirements, except analysis of samples, information was obtained from public literature.

ECOLOGICAL EFFECTS

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

TOXICOLOGY

EPA waived 40 CFR Part 158 requirements for reasons discussed in section III and relied on public literature.

ENVIRONMENTAL FATE

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

RESIDUE CHEMISTRY

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

The citations listed throughout this document and Appendix C were used to support these decisions.

APPENDIX C

ETHYLENE BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting the Reregistration of Ethylene

GUIDE TO APPENDIX C

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

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

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

4. FORM OF ENTRY. In addition to the MRID, each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

   b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the

document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

APPENDIX C

ETHYLENE BIBLIOGRAPHY

MRID Citation

41600901 Weatherson, I. (1990) Ethylene: Product Chemistry: Product Identity and Composition: Lab Project Number: RR-2. Unpublished study prepared by Technology Services Group, Inc. 44 p.

41600902 Weatherson, I. (1990) Ethylene: Product Chemistry: Analysis and Certification of Product Ingredients: Lab Project Number RR-3. Unpublished study prepared by Technology Services Group, Inc.

41644201 Weatherson, I. (1988) Product Chemistry: Physical and Chemical Characteristics of Ethylene: Lab Project Number. Unpublished study prepared by Technology Services Group, Inc. 6 p.

41970001 Hawley, G. (1991) Ethylene--physical/chemical properties. Condensed Chemical Dictionary. 8 edition. 8 p.

41970002 Lewis, B., Von Elbe, G. (1991) Ethylene--flammability. Combustions, Flames and Explosions of Gases(3) 14 p.

41970003 Green, D.; Maloney, J. (1991) Ethylene--physical/chemical properties. Perry's Chemical Engineers Handbook (6): 19 p.

41970004 Weast, R. (1991) Ethylene--physical/chemical properties. CRC Handbook of Chemistry and Physics. 1 edition. 7 p.

42448501 Vilkas, A. (1992) Ethylene: Product Chemistry: Product Identity and Composition: study prepared by Union Carbide Industrial Gases, Inc. 9 p.

42448502 Vilkas, A. (1992) Ethylene: Product Chemistry: Analysis and Certification of Product Ingredients. Study prepared by Union Carbide Industrial Gases, Inc. 5 p.

APPENDIX D

PR Notice 91-2

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

PR NOTICE 91-2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

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

APPENDIX E

Pesticide Reregistration Handbook

United States Environmental Protection Agency
Office of Pesticide Programs
October 1991

EPA

Pesticide Reregistration Handbook

How to Respond to the Reregistration Eligibility Document (RED)

PESTICIDE REREGISTRATION HANDBOOK

HOW TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED)

OFFICE OF PESTICIDE PROGRAMS
ENVIRONMENTAL PROTECTION AGENCY
OCTOBER 1991

PRODUCT REREGISTRATION HANDBOOK

TABLE OF CONTENTS

PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its uses and its regulatory history; describes EPA's decision concerning the eligibility of the uses of the chemical for reregistration; and explains the scientific and regulatory bases for this decision. EPA's reviews[1] of the data by scientific discipline are available upon request. Appendices to the RED contain: (1) a Data Call-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

--whether all of the product specific data and labels/labeling are acceptable,

--whether all of the uses on the label/labeling are eligible,

--whether all of the active ingredients in the product are eligible, and

--if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be reregistered. Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as amendments in order to implement label changes required by the RED.

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1 summarizes how and when to respond to the RED. A step-by-step explanation follows.

Step 1. Are Expedited Label Changes Required? In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED. If expedited label changes are not required, go to Step 2.

a. Application for Registration (EPA Form 8570-1). Complete

and sign the form. In Section II, insert the phrase "Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)." Applications for expedited label changes will be processed as applications for amended registration. Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.

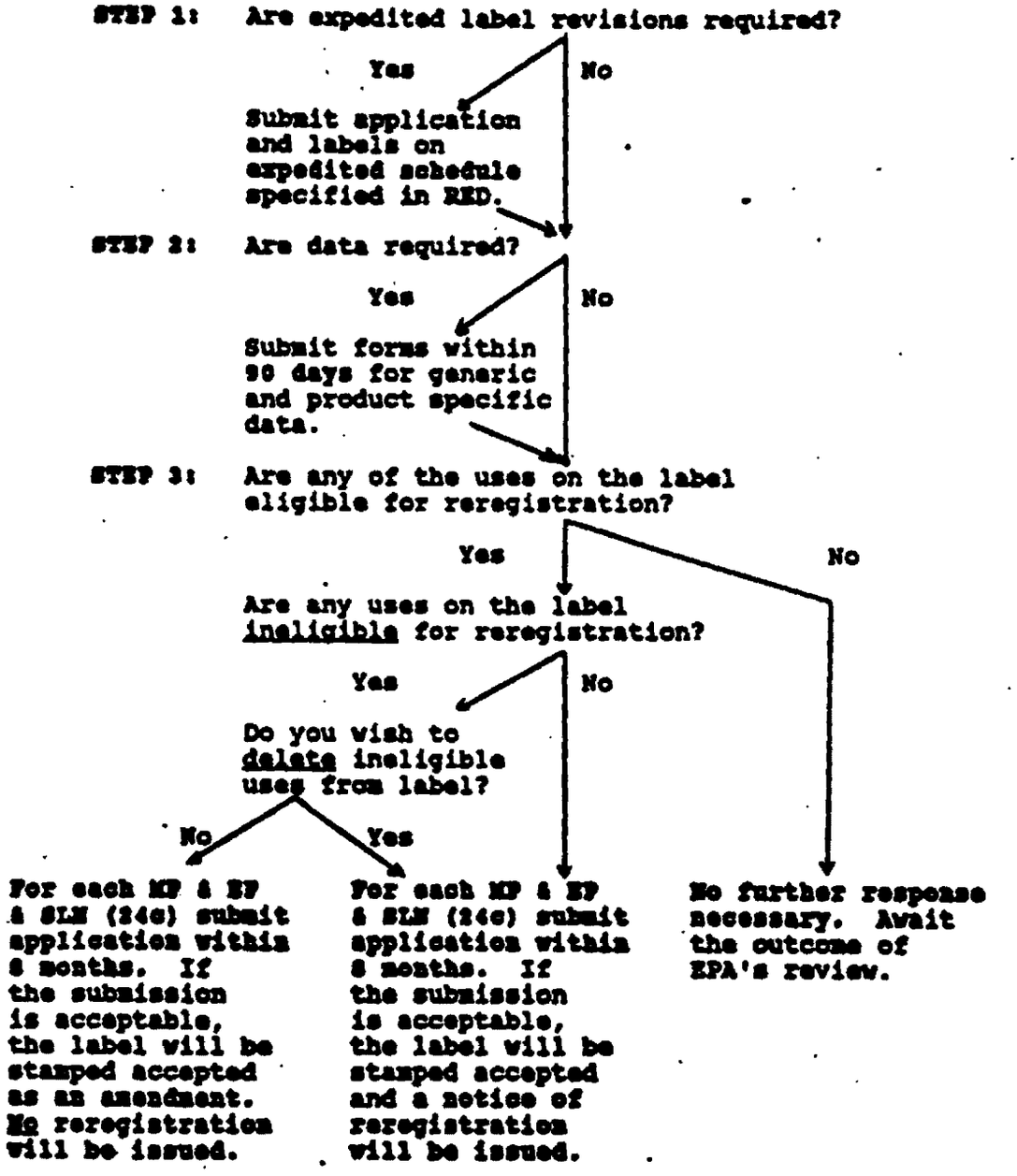
Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) and special local needs registrations (SLNs), must submit the items below for each product within 8 months of the date of issuance of the RED:

a. Application for Reregistration (use EPA Form 8570-1). Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase "Application for Reregistration." Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are ineligible uses on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).



c. Product Specific Data. You must follow the instructions in the Data Call-In Notice in the RED and in Section XII of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.

d. Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 88). Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation. If CSFs are not provided for the alternate formulas, they will not be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. Certification With Respect to Citation of Data (EPA Form 8570-31). This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

B. When No Response is Needed

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.

C. Where to Respond

By U.S. Mail:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing generic data. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing product specific data or labeling. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.

Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Call-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

B. Product Specific Data

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

1. Product Chemistry

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

a. Data

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together a being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

b. Inert Ingredients

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, a product containing a List 1 inert ingredient will not be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient. However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert may be reregistered if it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

2. Acute Toxicity

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each baatch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

3. Product Performance

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to EPA for review before tests are initiated.

a. Efficacy Data Submission Waiver Policy

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;

2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;

3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;

4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

C. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier. Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

C. Sample Label Formats--General Use & Restricted Use

D. Label Regulations (40 CFR 156.10)

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

Form Approved. OMB No. 2070-0060. Approval expires 8-30-90

EPA Confidential Statement of Formula

United States Environmental Protection Agency
Washington, DC 20460

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page ___ of ___

See Instructions on Back

1. Name and Address of Applicant/Registrant (Include ZIP Code)

2. Name and Address of Producer (Include ZIP Code)

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgt./Team No.

6. Country Where Formulated

7. Formula/Lot or Batch Number

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation (List an ordinarily hazardous ingredient. Also commonly accepted chemical name, trade name, and CAS number.)	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. Unit/Weight	14. Constant Limits a. by Weight b. Upper Limit c. Lower Limit		15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight: 100%

18. Signature of Approving Official

19. Title

20. Phone No. (Include Area Code)

21. Date

EPA Form 8570-4 (Rev. 3-88) Previous editions are obsolete.

Original and second copy to EPA
Third copy to Applicant

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product-specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

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. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that 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. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is normally required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

Item 7. WARNINGS AND PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 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 - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

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. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - 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. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - 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. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint 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.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation). If your product has been classified for restricted use, then these requirements apply:

1. All uses restricted. The following statements must be placed in a black box at the top of the front panel of the label and labeling:

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.

   b. The reason for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.

   c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. 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." The RED will specify what statement must be used.

2. Some but not all uses restricted. If the RED states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing 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 products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in

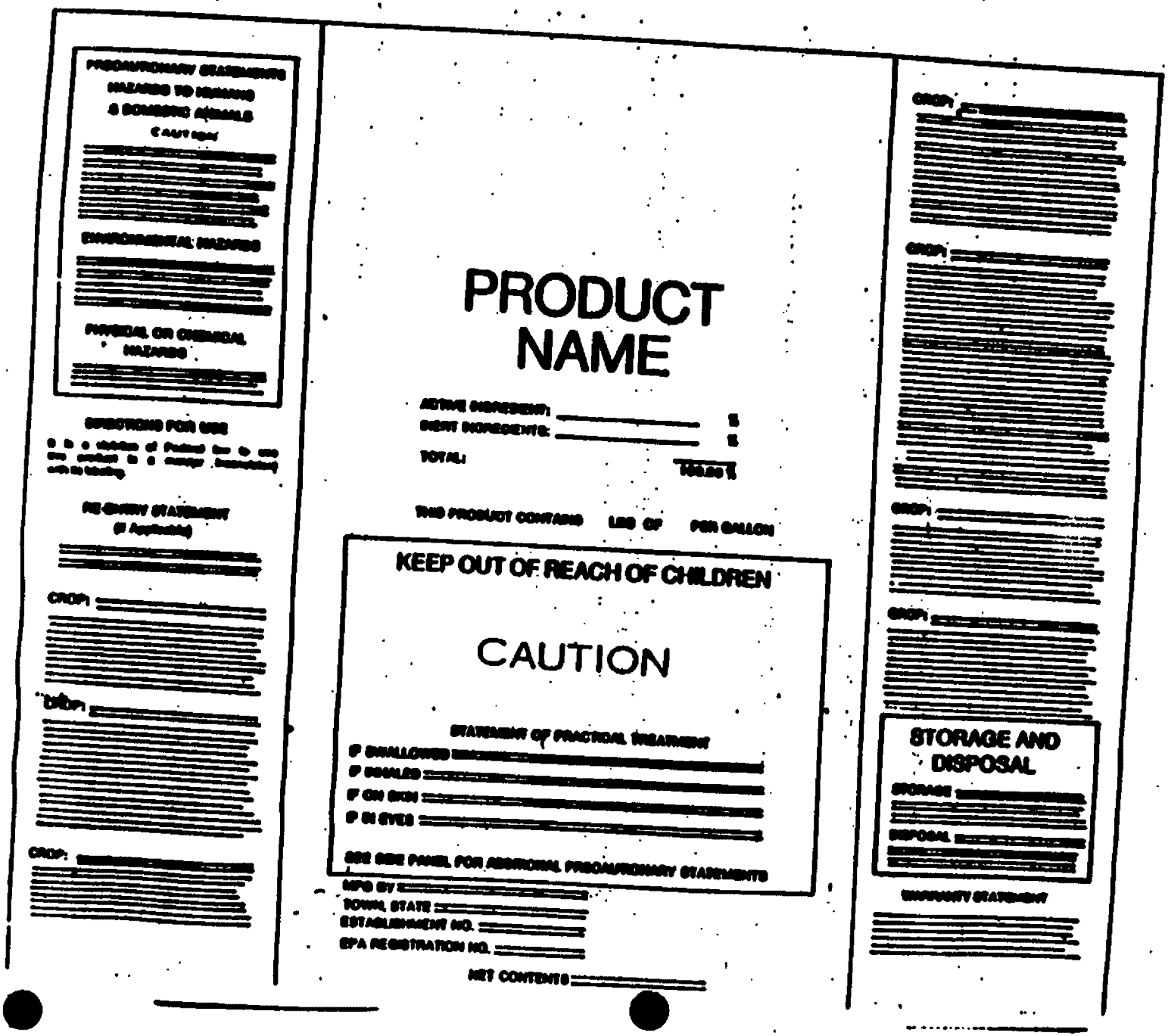
accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. 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 P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

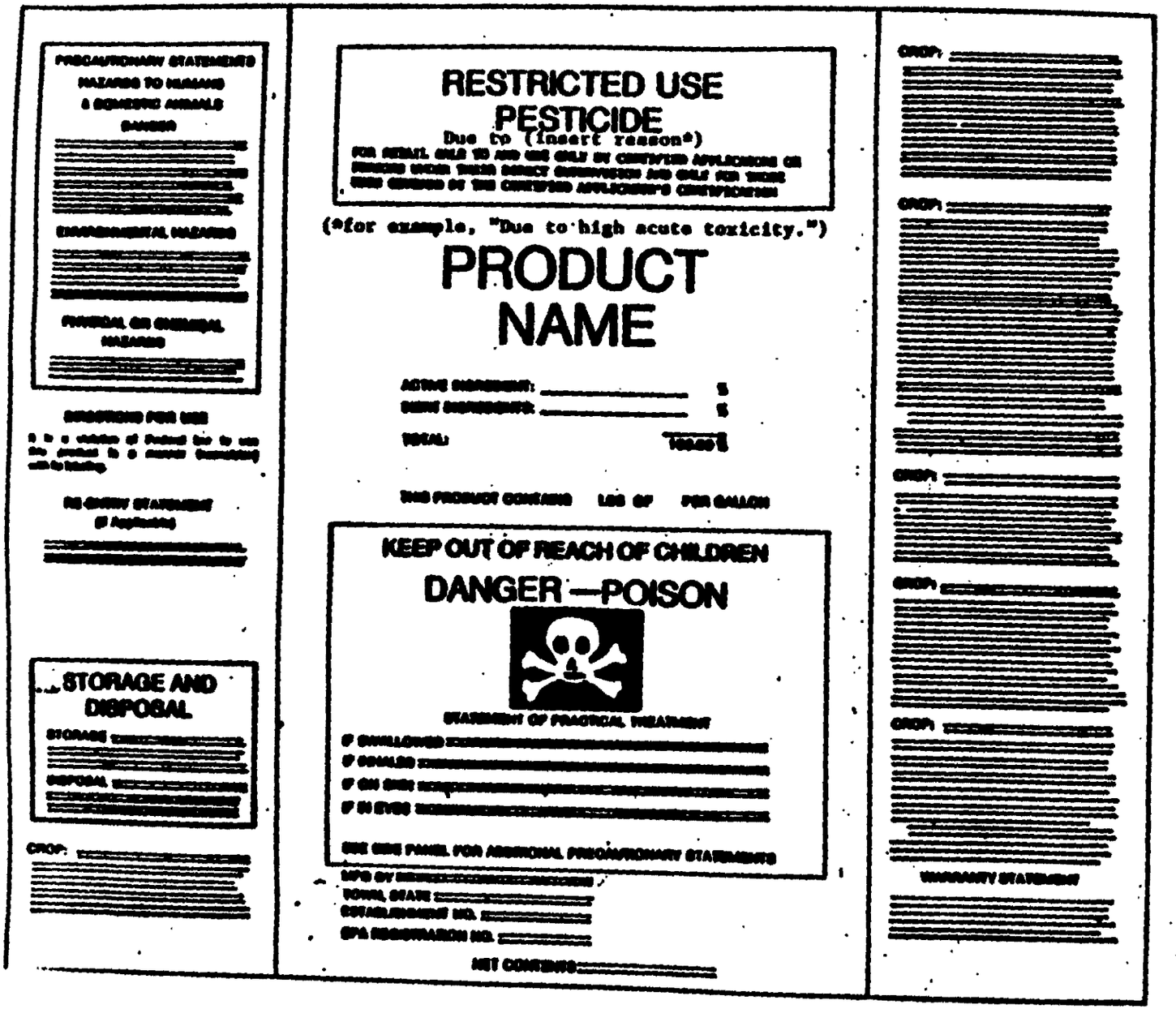
Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10(i)(2)]

COLLATERAL LABELING .

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or 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. Collateral labeling must be made part of the response to the RED and submitted for review.



LABEL FORMAT FOR UNCLASSIFIED PRODUCTS



LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED USE

submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard.

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 154.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 154.24 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136-136y.

§ 156.10 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 regu-

lations 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.

(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 § 152.240, 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 trade mark.* (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 § 152.132.

(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 semi-solid, 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 con-

tent 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:

(c) 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]."

(d) 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 mg/kg.	From 2,000 thru 20,000 mg/kg.	Greater than 20,000 mg/kg.
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	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	8
Above 10 to 15	12	8
Above 15 to 30	14	8
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 toxic 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.]

(2) *Environmental hazards.* Where a hazard exists to non target organisms including 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:

Flash point	Required text
(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	
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 paragraph (j) of this section 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 size as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(c) 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 paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "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 size as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), 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.

[40 FR 29268, July 3, 1975; 40 FR 31220, Aug. 1, 1975; 40 FR 34971, Aug. 21, 1975, as amended at 43 FR 5726, Feb. 9, 1978. Redesignated and amended at 53 FR 15951, 15960, May 4, 1988]

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