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		Use Limitations also see Abbreviations
								Allowed	Disallowed	
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 also 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

SEP 30 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency (the "Agency") has completed its reregistration eligibility decision on the pesticide active ingredient ethylene.

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient ethylene. The RED is the Agency's evaluation of ethylene, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for reregistration. Also enclosed is the **EPA RED facts** and the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 8 Months of the Date of this Letter

1. For **each product**, you must submit a completed **Application for Reregistration** (EPA Form 8570-1), **five copies of the label and labeling** revised as specified by the RED and in accordance with current requirements, **two completed copies of the Confidential Statement of Formula** (CSF) (EPA Form 8570-4).

2. The labeling and CSF which you submit for **each** product must **comply with P.R. Notice 91-2** (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the **nominal concentration** rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).

3. Send your Application for Registration to the **Registration Division Product Manager 22 (PM 22) who is assigned to the case, Cynthia Giles-Parker.** Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is RED-RD-PM22.

Questions on **confidential statement of formula and labeling** (for both End-use and Manufacturing-use products) should be directed to the **Registration Division Product Manager** for ethylene, **Cynthia Giles-Parker at (703) 305 -5540.** Questions on the **generic data requirements** should be directed to **Ruby Whiters, the Chemical Review Manager** in the **Special Review and Reregistration Division at (703) 308-8079.**

The Agency is prepared to meet with any registrants who have questions about responding to the ethylene RED. **If you wish to meet with the Agency, you must contact Mrs. Cynthia Giles-Parker within two weeks of your receipt of the RED.** The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,

Peter Caulkins for

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

registered uses of ethylene do not pose an unreasonable risk to the environment.

Additional Data Required

EPA has waived all generic (that is, active ingredient- specific) data requirements for ethylene except for technical chemistry studies, which have been received and reviewed.

Product Labeling Changes Required

The labels of all registered ethylene products must comply with EPA's current pesticide labeling requirements. A summary of the label additions/changes required for ethylene technical or manufacturing use products appears in the RED.

The following additions/changes are required in the labeling of ethylene end-use products:

- The signal word is "DANGER".
- The Precautionary Statement 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."
- The First Aid Statement of Practical Treatment 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."
- 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."

Regulatory Conclusion

- All registered pesticide products containing the active ingredient ethylene are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration. These products will be reregistered once the required confidential statement of formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for ethylene during a 60-day time period, as announced

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

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

For more information about ethylene or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual ethylene products, please contact PM Team 22, Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-5540.

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

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).

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

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

APPENDIX E

Pesticide Reregistration Handbook

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

SEP 30 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency (the "Agency") has completed its reregistration eligibility decision on the pesticide active ingredient ethylene.

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient ethylene. The RED is the Agency's evaluation of ethylene, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for reregistration. Also enclosed is the **EPA RED facts** and the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 8 Months of the Date of this Letter

1. For **each product**, you must submit a completed **Application for Reregistration** (EPA Form 8570-1), **five copies of the label and labeling** revised as specified by the RED and in accordance with current requirements, **two completed copies of the Confidential Statement of Formula** (CSF) (EPA Form 8570-4).

2. The labeling and CSF which you submit for **each** product must **comply with P.R. Notice 91-2** (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the **nominal concentration** rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).

3. Send your Application for Registration to the **Registration Division Product Manager 22 (PM 22) who is assigned to the case, Cynthia Giles-Parker.** Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is RED-RD-PM22.

Questions on **confidential statement of formula and labeling** (for both End-use and Manufacturing-use products) should be directed to the **Registration Division Product Manager** for ethylene, **Cynthia Giles-Parker at (703) 305 -5540.** Questions on the **generic data requirements** should be directed to **Ruby Whiters, the Chemical Review Manager** in the **Special Review and Reregistration Division at (703) 308-8079.**

The Agency is prepared to meet with any registrants who have questions about responding to the ethylene RED. **If you wish to meet with the Agency, you must contact Mrs. Cynthia Giles-Parker within two weeks of your receipt of the RED.** The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,

Peter Caulkins for

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

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

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.

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III. REQUIREMENTS

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

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Anne E. Lindsay

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

APPENDIX E

Pesticide Reregistration Handbook

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. # Apps	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ 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		Use Limitations also see Abbreviations
								Allowed	Disallowed	
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		Use Limitations also see Abbreviations
								Allowed	Disallowed	
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.

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

SEP 30 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency (the "Agency") has completed its reregistration eligibility decision on the pesticide active ingredient ethylene.

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient ethylene. The RED is the Agency's evaluation of ethylene, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for reregistration. Also enclosed is the **EPA RED facts** and the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 8 Months of the Date of this Letter

1. For **each product**, you must submit a completed **Application for Reregistration** (EPA Form 8570-1), **five copies of the label and labeling** revised as specified by the RED and in accordance with current requirements, **two completed copies of the Confidential Statement of Formula** (CSF) (EPA Form 8570-4).

2. The labeling and CSF which you submit for **each** product must **comply with P.R. Notice 91-2** (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the **nominal concentration** rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).

3. Send your Application for Registration to the **Registration Division Product Manager 22 (PM 22) who is assigned to the case, Cynthia Giles-Parker.** Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is RED-RD-PM22.

Questions on **confidential statement of formula and labeling** (for both End-use and Manufacturing-use products) should be directed to the **Registration Division Product Manager** for ethylene, **Cynthia Giles-Parker at (703) 305 -5540.** Questions on the **generic data requirements** should be directed to **Ruby Whiters, the Chemical Review Manager** in the **Special Review and Reregistration Division at (703) 308-8079.**

The Agency is prepared to meet with any registrants who have questions about responding to the ethylene RED. **If you wish to meet with the Agency, you must contact Mrs. Cynthia Giles-Parker within two weeks of your receipt of the RED.** The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,

Peter Caulkins for

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (H-7508W) | EPA-738-F-92-012 September 1992

EPA R.E.D. FACTS

Ethylene

Pesticide Reregistration

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

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

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

Use Profile

The pesticide ethylene is registered for use as a plant growth regulator and a herbicide. Ethylene is used commercially as a ripening agent for fruits and vegetables, a curing agent for tobacco, and a flower-producing agent in pineapples. It also is used to control witchweed in corn, cotton, peanuts and soybeans.

Regulatory History

The first pesticide product containing ethylene as an active ingredient was registered in December 1971. In May 1990, EPA designated ethylene as a biorational pesticide because it is naturally occurring and has a nontoxic mode of action in controlling target pests. Currently, eight pesticide products containing ethylene are registered with EPA.

Ethylene is exempt from the requirement of a tolerance (or maximum residue level) when used as a plant growth regulator on fruit and vegetable crops, or when injected into the soil to cause premature germination of witchweed, as part of the U.S. Department of Agriculture (USDA) witchweed control program. (Please see 40 CFR 180.1016.)

Human Health Assessment

Toxicity

EPA used information from the published literature rather than requiring new studies from registrants to assess the toxicity of ethylene.

Ethylene is a gas; therefore, the only exposure of toxicological concern is exposure to the lungs. Ethylene is naturally occurring and has been used widely as an anesthetic since 1923 without reports of significant toxicity. Therefore, EPA concludes that ethylene will be nontoxic to humans under its approved conditions of use as a plant growth regulator and in witchweed control programs.

Dietary Exposure

Ethylene is exempt from tolerance requirements, as mentioned earlier. EPA is requiring no residue data for reregistration because ethylene poses no dietary risk concerns.

Occupational and Residential Exposure

EPA has waived requirements for applicator and residential exposure studies because ethylene poses no mammalian toxicity concerns. In addition, due to its high volatility, people are not likely to be exposed to ethylene once it has been applied to fruit, vegetables or soil.

Human Risk Assessment

The potential risks to people from the pesticide uses of ethylene are considered negligible because ethylene is of low toxicity, high volatility (so exposure to treated foliage and foods as well as skin and lungs is minimal), and has had years of safe use as an anesthetic.

Environmental Assessment

Environmental Fate

Since ethylene is a biorational pesticide, environmental fate studies would not be required unless adverse effects on fish and wildlife were noted in ecological effects studies. As explained below, all ecotoxicity studies have been waived. Therefore, environmental fate studies are not required.

Ecological Effects

EPA has waived the ecological effects data requirements for both the indoor and outdoor uses of ethylene. Because it is a volatile gas, ethylene used indoors is not likely to result in exposure to nontarget species. The outdoor uses, soil injection and pineapple sprays, will result in only negligible exposure to aquatic and terrestrial organisms. Ethylene is naturally occurring and of low toxicity. Therefore, no data are required for reregistration of the outdoor uses.

Environmental and Ecological Risk Assessment

Ethylene is a naturally occurring, volatile gas, regarded as a biorational pesticide due to its low toxicity. Therefore, EPA finds that the