



US Environmental Protection Agency Office of Pesticide Programs

BIOPESTICIDE REGISTRATION ACTION DOCUMENT

1- Methylcyclopropene (PC Code 224459)

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(PC Code 224459)**

**U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Methylcyclopropene
(PC Code 224459)**

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I. Executive Summary

A. IDENTITY

Under normal environmental conditions, the active ingredient methylcyclopropene is a gas. End-use products EthylBloc®, SamartFresh™, SmartTabs™ and EthylBloc™ Sachet contain respectively 0.14%, 3.3%, 0.63% and 0.014% of 1- methylcyclopropene (hereafter referred to as methylcyclopropene and abbreviated as 1-MCP). When the product is mixed with water or a buffer solution, it releases the gas 1-MCP. The end-use product is manufactured by an integrated process. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

B. USE/USAGE

1-MCP is to be used in confined areas to extend the life and usefulness of fresh cut flowers and potted flowering, bedding, nursery and foliage plants and harvested fruits and vegetable by inhibiting the negative effects of ethylene. Plants, fruits and vegetable are treated in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. The use is classified as indoor food and non-food crops application.

C. RISK ASSESSMENT

No unreasonable adverse effects are anticipated from aggregate exposure to 1-MCP. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

No toxicological endpoints were identified. Mammalian toxicology data requirements have been submitted and adequately satisfy data requirements to support the registration. Submitted data indicate Toxicity Category IV for acute oral and acute inhalation toxicity. Acute dermal toxicity data indicated a Toxicity Category III. The data reported for primary eye irritation and dermal irritation studies showed that the test substance was minimally irritating, and was given a Toxicity Category III for eye irritation and Toxicity IV for dermal irritation. Moreover, the mammalian mutagenicity studies submitted, demonstrated that 1-MCP was not a mutagenic agent.

b. Human Exposure

Human exposure would be very low because of the absence of human activity in the enclosed and fairly gas tight areas where 1-MCP is used. The primary source for human exposure to 1-MCP will be from ingestion of food commodities treated by 1-MCP. However, residues on these commodities

are expected to be negligible. Moreover, the label's mitigating language and the quick dissipation of 1-MCP following its application reduce further the chances of human exposure.

c. Risk Assessment

EPA has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. Risk to applicators is mitigated as long as the product being registered at this time is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to label instructions. The Agency has considered 1-MCP in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effects from the use of this product.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

No toxic endpoints were identified.

b. Ecological Exposure

Information regarding nontarget organisms was waived based of the minimal exposure to 1-MCP. The enclosed areas treated which originally have a minimal nontarget organisms activity, are fairly gas tight to reduce leakage. As a result, exposure outside the treated areas can also be considered minimal.

c. Risk Assessment

Risk to nontarget organisms is expected to be minimal, due to the low chances of exposure to 1-MCP. As a result, EPA believes that the use of 1-MCP according to label use directions, should result in no significant adverse effects to wildlife.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

I. Overview

A. ACTIVE INGREDIENT OVERVIEW

| | |
|-------------------------------|--|
| Chemical Name: | 1-Methylcyclopropene |
| Molecular Formula: | C ₄ H ₆ |
| Chemical Family: | Methylcyclopropene |
| Trade and Other Names: | 1-MCP |
| CAS Registry Number: | 3100-04-7 |
| OPP Chemical Code: | 224459 |
| Basic Manufacturer: | AgroFresh, Inc / Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19105 |

B. USE PROFILE

The following, is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Plant Growth Regulator

Use Sites: Enclosed indoor use on fresh cut flowers and potted flowering, bedding, nursery foliage plants, and fruits and vegetables. Plants are treated in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers, and fruits storage areas.

Target: Inhibit the effect of Ethylene

Formulation Types: Powder

Timing: Application should be made just prior to harvest, immediately after harvest, prior to shipment, upon arrival from the supplier, and/or just prior to sale. Repeat at weekly intervals.

C. DATA REQUIREMENTS

The mammalian toxicology and ecological effects data requirements for 1-MCP have been fulfilled. Product analysis data requirements are adequately satisfied. The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this chemical and recommends an unconditional registration of this new active ingredient for the proposed uses.

D. REGULATORY HISTORY

On September 27, 1997, the Agency received an application from Biotechnologies for Horticulture, Inc. to register EthylBolc® containing 0.43% of 1-methylcyclopropene as a plant growth regulator.

A notice of receipt of the application for registration of 1-methylcyclopropene as a new active ingredient was published in the Federal Register on March 10, 1999 (64 FR 11868) with a 30-day comment period. No comments were received as a result of this publication.

E. CLASSIFICATION

The Biochemical Classification Committee determined that the 1-MCP gas has not been shown to occur naturally, and can not be proved to fit the biochemical pesticide definition. However, the low use rates of 1-MCP and its non-persistence and non-toxic mode of action, make this plant growth regulator eligible for a reduced data set similar to that used for biochemical pesticides applied to non-food crops in greenhouses.

F. FOOD CLEARANCES/TOLERANCES

In April, 2000, the Agency received a petition from AgroFresh Inc., proposing the establishment of an exemption from the requirement of regulations for residues of the biochemical 1-MCP in or on all food commodities. A notice of filling was published in the Federal Register of June 21, 2000 (65 FR 38550).

The final rule establishing an exemption from the requirement of a tolerance for residues of 1-Methylcyclopropene in or on fruits and vegetables when used as a post harvest plant growth regulator, for the purpose of inhibiting the effects of ethylene, was approved and published in the Federal Register on July 26, 2002 (67 FR 48796).

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for 1-MCP are satisfied.

1. Product Identity and Mode of Action

a. Product Identity:

There is no TGAI for 1-MCP. The end-use product has to be mixed with water or a buffer solution in order to release the active ingredient (gas) 1-MCP which has the chemical formula C_4H_6 . End-use products EthylBloc®, SamartFresh™, SmartTabs™ and EthylBloc™ Sachet contain respectively 0.14%, 3.3%, 0.63% and 0.014% of 1-MCP. When the product is mixed with water or a buffer solution, it releases the gas 1-MCP. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

b. Mode of Action:

1-MCP which is considered a plant growth regulator, has a non-toxic mode of action. It acts as an inhibitor of ethylene by blocking the attachment of ethylene to tissue of plant, flower, vegetable or fruit, and thus prolongs the life of cut flowers and plants.

2. Food Clearances/Tolerances

The final rule establishing an exemption from the requirement of a tolerance for residues of 1-Methylcyclopropene in or on fruits and vegetables when used as a post harvest plant growth regulator, for the purpose of inhibiting the effects of ethylene, was approved and published in the Federal Register on July 26, 2002 (67 FR 48796).

3. Physical And Chemical Properties Assessment

Since there is no TGAI involved, the physical and chemical characteristics of the end-use product were submitted to support the registration. There are summarized in Table 1.

Table 1. Product chemistry data requirements

| GUIDELINE NO. | STUDY | RESULTS | MRID NO. |
|-------------------------------|---|---|-------------------------------------|
| 151B-10 151B-11 151B-12 | Product identity; Manufacturing process; Discussion of formulation of unintentional ingredients | Submitted data satisfies the data requirements for product identity, manufacturing process, and discussion of formation of impurities | 445170-01 444647-01 445170-02 |
| 151B-13 | Analysis of samples | Submitted data satisfy the data requirements for analysis of samples | 444647-02 |
| 151B-15 | Certification of limits | Limits listed in the CSF are adequate | 445170-03 |
| 151B-16 | Analytical method | G C / F I D | 44647-03 |
| 151B-17 | PHYSICAL / CHEMICAL PROPERTIES FOR THE EP | | |
| 151B-17(a) | Color | White | 445676-01 |
| 151B-17(b) | Physical State | Powder | 445676-01 |
| 151B-17© | Odor | Faint, sweet | 445676-01 |
| 151B-17(d) | Melting point | >300 °C ; color changes from white to brown at 260 °C. | 445676-01 |
| 151B-17(e) | Boiling point | Not Applicable | |
| 151B-17(f) | Density/Specific gravity | 0.634 g/ml at 25 °C | 445676-01 |
| 151B-17(g) | Solubility | 152 g/L water | 445676-01 |
| 151B-17(h) | Vapor Pressure | NA | |

| GUIDELINE NO. | STUDY | RESULTS | MRID NO. |
|---------------|-------------------------------|--|-----------|
| 151B-17(i) | pH | 3.92 (in a 5.02% aqueous solution | 445676-01 |
| 151B-17(j) | Stability | Stable between 0 and 37 °C, under artificial sunlight, and in aqueous solution | 445676-01 |
| 151B-17(k) | Flammability | Not Specified | |
| 151B-17(l) | Storage stability | Not Specified | |
| 151B-17(m) | Viscosity | NA | |
| 151B-17(n) | Miscibility | NA | |
| 151B-17(o) | Corrosion characteristics | Not Corrosive | 445676-01 |
| 151B-17(p) | Octanol/water partition coef. | NA | |

B. HUMAN HEALTH ASSESSMENT

The information submitted in support of the application for registration of the end use products adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for food and non-food indoor uses.

The overall toxicological risk from human exposure to 1-MCP is considered negligible.

1. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the active ingredient 1-methylcyclopropene.

a. Acute Toxicity

The registrant submitted acceptable acute toxicity studies. Based on a lack of mortality observed in albino rats orally dosed with 5000 mg/kg of powdered product EthylBloc®, the oral LD₅₀ was >5000 mg/kg; tox category IV. Based on a lack of mortality observed in albino rabbits dermally dosed with 2000 mg/kg of powdered product, the LD₅₀ was >2000 mg/kg; tox category III. Based on a lack of mortality observed in albino rats exposed to 165 ppm of 1-MCP gas for 4

hours, the LC₅₀ was >165 ppm; tox category IV. Ocular instillation of 0.1 ml of powdered product caused mild to moderate eye irritation symptoms (redness, chemosis) which cleared by 72 hours posttreatment; tox category III. Dermal application of 0.5 g of powdered product did not cause any dermal irritation symptoms up to 72 hours postdosing; tox category IV. Based on the data, the test substance is not considered to be a contact sensitizer. No hypersensitivity incidents have been reported. Additionally, 4100 person hours of 1-MCP exposure have been experienced by humans without any known 1-MCP-induced health related problems being reported.

b. Mutagenicity and Developmental Toxicity

The registrant submitted acceptable mammalian and non-mammalian mutagenicity studies for 1-MCP. Based on the data obtained from the *Salmonella typhimurium* microsome reverse mutation assay, 1-MCP did not induce positive increases in the number of revertants. The data obtained from the mouse lymphoma forward mutation assay showed that 1-MCP did not induce a significant increase in mutant cells relative to controls; no dose-response effects nor cell toxicity effects were observed. Based on the data obtained from the *in vivo* mouse microsomal assay, 1-MCP did not induce increases in micronucleated PCEs (polychromatic erythrocytes) relative to vehicle controls; no bone marrow toxicity [measured as a decrease in PCE:NCE (normochromatic erythrocytes) ratio] was observed for any dose of test substance. Based on a lack of statistically significant data obtained from a reverse-mutation assay study a mouse lymphoma forward mutation study assay, and a mouse micronucleus study, 1-MCP is not considered a mutagen.

Mammalian toxicity data for EthylBloc® submitted are summarized in Table 2.

Table 2. Toxicity data requirements

| GUIDELINE NO. | STUDY | RESULTS | MRID NO. |
|---------------|-----------------------------------|-----------------------|-----------|
| TIER I | | | |
| 152-10 | Acute oral toxicity in rats | Toxicity Category IV | 444647-04 |
| 152-11 | Acute dermal toxicity in rabbits | Toxicity Category III | 444647-05 |
| 152-12 | Acute inhalation toxicity in rats | Toxicity Category IV | 444647-06 |

| GUIDELINE NO. | STUDY | RESULTS | MRID NO. |
|---------------|---|--|------------------------|
| 152-13 | Primary eye irritation in rabbits | Toxicity Category III | 444647-07 |
| 152-14 | Primary dermal irritation in rabbits | Toxicity Category IV | 444647-08 |
| 152-15 | Dermal sensitization in guinea pigs | Not a sensitizer | 445170-05 |
| 152-16 | Hypersensitivity incidents | No hypersensitivity incidents observed | 445170-06 |
| 152-17 | Genotoxicity - <i>Salmonella typhimurium</i> gene mutation assay | Not mutagenic | 444647-09 |
| 152-18 | Cellular immune response | Waived | |
| 152-19 | Mutagenicity: * Mouse Lymphoma forward mutation * <i>In vivo</i> mouse micronucleus assay | Not mutagenic | 444647-10 444647-11 |

c. Subchronic Toxicity

A 90 - day feeding study was not required because of the non-food use of 1-MCP. Moreover, the 90 - day dermal and inhalation toxicity studies are not required because the proposed use

pattern does not result in prolonged exposure at concentrations that are likely to be toxic. The immunotoxicity study (cellular immune response study) was waived based on the minimal potential for exposure and the low toxicity of 1-MCP shown in the studies submitted.

d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

e. Effects on the Endocrine Systems

The Agency is not requiring information on the endocrine effects of this compound at this time. EPA has considered, among other relevant factors, available information concerning whether 1-MCP has an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known evidence so far that the active ingredient act as an endocrine disruption in humans. No adverse effects to the endocrine system are known or expected.

2. Dose Response Assessment

No toxicological endpoints are identified.

3. Dietary Exposure and Risk Characterization

Dietary exposure is unlikely to occur because of the non-food use of 1-MCP. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Human exposure to 1-MCP is not expected in these areas.

a. Occupational Exposure

Based on its low toxicity and its use on ornamentals intended for aesthetic purposes, 1-MCP is not subject to the Worker Protection Standards (WPS). Moreover, the possibility for dermal, eye and inhalation exposure, is mitigated as long as the product is used according to label directions which

recommends the use of protective equipment by users, posting signs to keep people out of treated areas, and allowing proper ventilation time before permitting human activity in the treated areas.

b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed labels.

5. Food and Drinking Water Exposure

i. Food-From food and feed uses. The primary source for human exposure to 1-MCP will be from ingestion of the following raw food commodities and the processed food commodities derived from: apples, melons, tomatoes, pears, avocados, mangoes, papayas, kiwi, plums, apricots and persimmons. Studies submitted showed residues in treated apples to be extremely low (average residue was 0.004 ppm using an exaggerated treatment rate of 1,200 parts per billion (ppb) versus the 1,000 ppb proposed label rate). A worst-case scenario (using the 0.004 ppm average residue concentration found in treated apples and assuming that concentration is present in 100% of the diet regardless of crops treated) indicates that a daily diet of 1.5 kg/day could contain 0.006 mg 1-MCP. For the general population (assuming an average body weight of 60 kg), this would represent a daily intake of 0.0001 mg 1-1-MCP/kg body weight which is 90,000 to 150,000-fold less than the 9-15 mg/kg NOAEL indicated in the 90-day inhalation study. Residues in other treated commodities are expected to be similar or even lower since the highest treatment rate is recommended for apples. Processing would be expected to further lower the residue levels in processed food commodities.

ii. Drinking water exposure. Since 1-MCP will only be used on post-harvested fruits and vegetables in enclosed storage areas, there is little if any, potential for drinking water exposure.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

There is reasonable certainty that no harm will result from aggregate exposure to residues of 1-MCP to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV) and the minimum exposure associated with 1-MCP's use.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that 1-MCP is practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, based on the lack of observed developmental toxicity and

extremely low exposure, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to 1- 1-MCP residues.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the applicators subpopulations via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for 1-MCP showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category III), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

8. Cumulative Effects

1-MCP is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity.

9. Risk Characterization

The Agency has considered 1-MCP in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of 1-MCP when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The end use products are intended for use in food and non-food enclosed areas. When applied according to the proposed label, no direct exposure of birds, aquatic organisms and non-target insects to 1-MCP is expected to occur. Thus, 1-MCP's potential environmental/ecological effects are likely to be negligible. As a result, non-target organism/ecological effects studies were not required for this particular use of 1-MCP.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in Tier I studies.

Risk to nontarget species is minimal due to the lack of exposure, low toxicity, use pattern, and application methods.

3. Ecological Exposure and Risk Characterization

No potential for exposure exists to nontarget wildlife as a result of 1-MCP's use.

D. EFFICACY DATA

No efficacy data are required, since no public health uses are involved.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria “A” above, 1-MCP is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria “B” is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, will extend the life and usefulness of ornamentals as claimed satisfying Criteria “C”. Criteria “D” is satisfied in that the toxicological properties of this product are less toxic than any other conventional pesticide product currently in use.

Therefore, 1-MCP is eligible for registration. Registered use is listed in Table 4, Appendix A.

B. REGULATORY POSITION

1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that unconditional registration of 1-MCP is appropriate.

2. CODEX Harmonization

No Codex maximum residue levels are established for residues of 1-MCP in or on any food or feed crop. There are no established tolerances or exemptions from tolerance for 1-MCP in the United States. The Agency has classified 1-MCP as a biochemical pesticide.

3. Nonfood Re/Registrations

There are no non-food issues at this time. All the uses are listed in Appendix A, Table 4.

4. Risk Mitigation

Since there are no risk issues, risk mitigation measures are not required at this time.

5. Endangered Species Statement

The Agency has determined there will be No Adverse Effect (NAE) on endangered species or other non-target organisms following the use of products containing 1-MCP. There is no evidence of toxicity to any non-target organisms or effects on critical habitat based on data obtained from a review of the available literature. Exposure of non-target organisms to 1-MCP is minimal. The enclosed areas treated which originally have no nontarget organisms activity, are fairly gas tight to reduce leakage. As a result, exposure outside the treated areas can also be considered minimal.

The Agency has no evidence to believe that any endangered or threatened species will be adversely affected if products containing 1-MCP are used as labeled. The Agency has made a no effect finding for the use pattern of 1-MCP. Thus, no labeling is required for endangered or threatened species at this time.

C. LABELING RATIONALE

It is the Agency's position that the labeling for EthylBloc® containing 0.43% of 1-methylcyclopropene complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

This product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for 1-MCP product and concluded that the proposed precautionary labeling (i.e. Signal Word, Statement of Practical Treatment and other label statements) adequately mitigates the risks associated with the proposed uses.

End-Use product Precautionary Labeling: For EthylBloc®, "CAUTION". Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse.

d. Spray Drift Advisory

No spray drift advisory statement is necessary for this use

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: Because 1-MCP is exclusively intended for indoor use, the environmental hazard statement is not required on the end-use product's label.

3. Application Rate

It is the Agency's position that the labeling for the pesticide product containing 1-MCP complies with the current pesticide labeling requirements. The Agency has not stipulated a maximum number of applications for the active ingredient. However, each approved product has a specified maximum required amount of the active ingredient per application.

As an example, here is the application rates requirements for the product EthylBolc®:

At a temperature of at least 55°F, 1 scoop (1.5 grams) of EthylBolc® is to be mixed with 1 ounce of the buffer solution in order to treat a space of 100 cubic feet. The treatment time should be between 4 to 8 hours. At this dosage, a rate of 900 part per billion (ppb) of 1-MCP will be released. If a longer treatment time (12 to 16 hours) is needed, the same dosage of EthylBolc® (1.5 grams in 1 ounce of the buffer solution) can be used to treat an enclosed area of 200 cubic feet. In this case, 1-MCP release will be a level of 450 ppb.

At temperatures between 35° and 55°F, 1 scoop of EthylBloc® is to be mixed in 1.5 ounce of the buffer solution, and used to treat an enclosed space of 100 cubic feet. The amount of 1-MCP released will be at 900 ppb. A minimum treatment time of 10 hours is required under these conditions.

D. LABELING

(1) Product name: **EthylBloc®**

Active Ingredient:

1-methylcyclopropene..... 0.43%
Other Ingredients 99.57%

Total 100.00%

(2) Product name: **SmartFresh™**

Active Ingredient:

1-methylcyclopropene..... 3.3%
Other Ingredients 96.7%

Total 100.00%

(3) Product name: **SmartFresh™ SmartTabs**

Active Ingredient:

1-methylcyclopropene..... 0.63%
Other Ingredients 99.37%

Total 100.00%

(4) Product name: **Manufacturing Use Product - SF**

Active Ingredient:

1-methylcyclopropene..... 4.5%
Other Ingredients 95.5%

Total 100.00%

(5) Product name: **EthylBloc™ Sachet**

Active Ingredient:

1-methylcyclopropene..... 0.014%
Other Ingredients 99.986%

Total 100.00%

Signal word is "CAUTION". Eye irritation warning is appropriate.

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)

V. Actions Required by Registrants

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

vi. Appendix A

Table 4 lists the use sites for the product. The label for the product is also attached.

Table 4. Use Site Registration/Reregistration

| | |
|---|---|
| EthylBloc® <u>Use Sites</u> Fresh cut flowers and potted flowering, bedding, nursery and foliage plants. | Official date registered: April 22, 1999 |
| SmartFresh™ Technology <u>Use Sites</u> Post-harvest Fruits (apples, melons, tomatoes, pears, avocados, mangoes, papayas, kiwifruit, plums, apricots and persimmons) | Official date registered: July 17, 2002 |
| SmartFresh™ SmartTabs <u>Use Sites</u> food commodities derived from: apples, melons, tomatoes, pears, avocados, mangoes, papayas, kiwifruit, plums, apricots and persimmons | Official date registered: March 11, 04 |
| Manufacturing- Use Product SF | Official date registered: January 30, 2004 |
| SmartFresh™ Sachet <u>Use Sites</u> Fresh cut flowers and potted flowering and foliage plants. | Official date registered: February 3, 2006 |