National Organic Program-Submission of Petitions of Substances for Inclusion on or Removal from the National List of Substances Allowed and Prohibited in Organic Production and Handling

PETITION

Item A—Please indicate which section or sections the petitioned substance will be included from the National List.

- Synthetic substances allowed for use in organic crop production, § 205.601.

Item B—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned:

1. **The substance's chemical or material common name.**

   Chemical name: 1-Methylcyclopropene, 1-MCP
   Trade name: SmartFresh™ (1-MCP stabilized in alpha cyclodextrin)

2. **The manufacturer's or producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.**

   Islechem LLC
   2801 Long Road
   Grand Island, NY 14072-1244

3. **The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (*e.g.*, cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (*e.g.*,ingredient, flavoring agent, emulsifier, processing aid).**

   Current use: 1-MCP is regulated as a plant growth regulator under FIFRA. EPA has classified 1-MCP as a biopesticide and is currently registered for use in about 50 countries for its post-harvest benefits on apples.
   Application: 1-MCP delays fruit ageing and over-ripening of fruit caused primarily by ethylene, thereby helps maintain the freshness and eating quality of fresh unprocessed apples during storage and transportation. Post-harvest handling of apples with 1-MCP has proven to provide consumers with consistent quality apples throughout the year and reduce wastage. In addition, 1-MCP has been shown to reduce certain fruit disorders, such as scald. Some literature suggests that as a secondary benefit due to its effect in slowing down the ripening process, 1-MCP helps maintain the nutritional quality of the apples, especially antioxidant content.

4. **A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.**

1-MCP will be used for post-harvest handling of apples in sealed storage rooms. 1-MCP has shown to have a non-toxic mode of action, namely binding to ethylene receptor sites and slows ethylene activity. Ethylene is a natural plant hormone produced internally in apples, and is responsible in triggering ripening associated processes in the field such as color and flavor development, but also causes the fruit to soften and lose eating quality in storage. The ethylene receptor sites in the fruit recognize and bind ethylene. 1-MCP is a hydro-carbon gas similar to ethylene; similarly, the ethylene receptor sites in the fruit also bind 1-MCP. The ethylene receptor sites have a higher affinity for 1-MCP than ethylene and preferentially bind 1-MCP to the sites. This preference results in slowing down the ethylene response and slows down the continuation of ripening processes, thereby increasing the time it takes for the fruit to soften and rot. SmartFresh, is basically 1-MCP complexed with natural sugars (alpha cyclodextrin), as a means to stabilize the gas.

5. **The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.**

1-MCP is manufactured by a proprietary process following the guidelines of Responsible Care®, sponsored by the American Chemistry Council. Responsible Care is a global initiative that is practiced currently in 52 countries, which share a common commitment to advancing the safe and secure management of chemical products and processes. Patents are available in public domain explaining the manufacture of 1-MCP/ alpha-cyclodextrin complex (*US Patent 6017849; US Patent 2002/0043730 A1*). Alpha-cyclodextrin is one of a family of cyclic sugars called cyclodextrin formed by connecting a group of sugar molecules together in a ring form. The alpha-cyclodextrin is also used as a soluble dietary fibre in food products.

During the manufacture of 1-MCP, which has been optimized, perfected and effectively done over 15 years, there is no evidence of environmental contamination. 1-MCP is a gas and is directly trapped into the cyclic sugar. AgroFresh maintains responsibility for chemicals from the starting raw materials, through the safe disposal of the waste streams. This "cradle to grave" philosophy guides all chemical processes.

A closed system is used to manufacture and trap the 1-MCP in alpha cyclodextrin. A closed system minimizes any emissions to the atmosphere. There has been no evidence of environmental contamination as noted earlier.

Step 1: 1-MCP gas formation: The starting materials for 1-MCP production are mixed (*published in US Patent 6017849*) and fed to a small reactor and heated slightly above atmospheric pressure.
Step 2: 1-MCP gas purification: The mixture from step 1is purified with cold water in a small packed column resulting in purified 1-MCP gas. By combining the waste stream from steps 1 and 2, the overall waste is reduced.
Step 3: Formation of 1-MCP- alpha cyclodextrin complex: The high purity 1-MCP gas from step 2 is bubbled into a solution of alpha cyclodextrin, a large sugar sourced from a fermentation process, continuously forming the crystalline 1-MCP-alpha cyclodextrin complex.

Step 4: Dewatering, solvent wash, and drying: The crystalline complex from step 3 contains water and is dried to the final powder. The powder is then blended with sugar to achieve the final 3.3% 1-MCP SmartFresh powder formulation. The dried product is stored in well sealed, reusable, poly drums.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.

The documents shown below are all attached in the appendix

- EPA Reg. No. 71297-2 (http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:102:::NO::P102_REG_NUM:71297-2)
- 1-MCP - Biopesticide Registration Action Document
- 1-MCP - Tolerance Requirement Exemption 7/02
- 1-MCP - Registration of the Pesticide Product SmartFresh (EPA Reg. No. 71297-2), which Represents a Major Change in Labeling for the Active Ingredient 1-Methylcyclopropene 9/02
- FAO specifications and evaluations for agricultural pesticides: 1-Methylcyclopropene

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

- 1-MCP was registered as a 1-MCP- alpha cyclodextrin complex in the Biochemical division (BPPD) of the EPA under the trade name "SmartFresh" on July 17, 2002 (EPA Reg. No. 71297-2; attached)
- 1-MCP leaves no detectable residues and has been declared exempt from the requirement of setting a tolerance (40 CFR 180.1220). See attached.
- 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; amended April 09, 2008 (https://www.federalregister.gov/articles/2008/04/09/E8-7458/1-methylcyclopropene-amendment-to-an-exemption-from-the-requirement-of-a-tolerance; 73 FR19147)
- SmartFresh is registered and approved for use in all 50 states (CA and WA registration attached for reference)

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.

CAS registry number: 3100-04-7

9. The substance's physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/or

manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

Physical properties: BRAD report attached

Color	White
Physical state	Powder
Odor	Faint, sweet
Melting point	>300° C; color changes from white to brown at 260° C
Boiling point	NA
Density/ Specific gravity	0.634 g/ mL at 25° C
Solubility	152 g/L water
Vapor pressure	NA
pH	3.92 (in 5.02% aqueous solution)
Stability	Stable between 0 and 37° C under artificial sunlight, and in aqueous solution
Flammability	Not specified
Storage stability	Not specified
Viscosity	NA
Miscibility	NA
Corrosion characteristics	
Octanol/ water partition coef.	NA

Chemical mode of action:

The chemical mode of action of 1-MCP in plants is both non-persistent and non-toxic. 1-MCP competes with ethylene for the ethylene receptor sites and due to its higher affinity selectively binds to the sites. 1-MCP has shown to demonstrate a bonafide ethylene effect (De Paepe A et al., J Exp Bot 56 (419): 2409-20 (2005); Li D et al., Phytochemistry 67 (7): 658-67 (2006). Ethylene is a natural plant hormone that is responsible for fruit ripening such as color and flavor development, and ethylene also continues its action causing fruit to soften, degrade, and rot. 1-MCP application timing is based on fruit maturity, and thus the mode of action does not stop the fruit from undergoing the natural physiological changes such as color or volatile development but rather helps in slowing down the further ripening of fruit by ethylene, once it is in storage(Liu K et al; Plant Mol Biol 58 (4): 447-64 (2005)).

Chemical interactions with other substances, especially substances used in organic production:

(a) Copper has been shown to destroy 1-MCP completely. Since application occurs after harvest and during a time when fruit reside in air-tight storage rooms for extended period, we expect no copper residue available on the fruit for interactions. We have not seen evidence of chemical reaction with other substances during post-harvest handling of apples.

(b) **Toxicity and environmental persistence:** 1-MCP has a non-toxic and non-persistent mode of action (see TOXNET, toxicology data network, (http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7517). Post-harvest handling of apples requires 1-MCP application in confined spaces, so its release to the outside of the apple rooms is limited. If released to air, 1-MCP will exist solely as a gas in the atmosphere and will be degraded in the

atmosphere and by reaction with photochemically-produced hydroxyl radicals (half-life: 4.4 hours).

(c) **Environmental impacts from its use and/or manufacture**: During the manufacture of 1-MCP there is no evidence of environmental impact, as a closed system is used to manufacture and efficiently trap 1-MCP. Further intensive safety audits are put in place during 1-MCP manufacture, which includes, QuEHST (Quality, Environment, Health, Safety and Technology) audit of manufacturers and formulators, HAZOP of the manufacturing process (Hazard and Operability analysis), Industry standard ventilation of the workspace, Waste incineration for most steps during production and Employee exposure monitoring to guarantee that employees are protected. The QuEHST is an extensive 105 page audit which focuses on the following area of the site's systems/location: Site factors (i.e. proximity to public), Security, Safety, Industrial hygiene, Environmental controls, Quality, Product integrity, and Distribution/logistics. During the manufacture process low environmental impact solvents are used and they are recycled for multiple use.

(d) **Effects on human health:** 1-MCP has been in use for more than 15 years and there is no evidence of any effect on human health. 1-MCP has a non-toxic mode of action, is shown to have low toxicity and no residues of 1-MCP have been found (see the attached BRAD). An exemption from the requirement of a tolerance is established for residues of 1-methylcyclopropene in or on fruits and vegetables when used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene (40 CFR 180.1220).

(e) **Effects on soil organisms, crops, or livestock:** 1-MCP is a gas at temperature above 0°C and is expected to volatilize from dry soil surfaces and water surfaces. 1-MCP has also shown to have high mobility in soil and Henry's Law constant ($4x10^{-2}$ atm-cu m/mole) indicates that volatilization from moist soil surfaces may occur. Moreover, 1-MCP is used in post-harvest handling of apples in airtight rooms for at least 12 hours to ensure that minimum to no 1-MCP applied (<1 ppm) is detected outside the room. 1-MCP mode of action is not relevant in animals, since ethylene receptors are not present in animal tissues. Also, 1-MCP has no detrimental effect on soil microorganisms.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

MSDS for SmartFresh is attached.
A substance report from the National Institute of Environmental Health Studies does not exist.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

1-MCP is the one of the most researched and documented compound globally due to its beneficial effects on fruits and vegetables, both as a tool to investigate its role in delaying ethylene mediated processes, and as a technology to maintain the produce quality. There were about 6700 hits on google scholar when searched for 1-MCP and apples and 482 references in science direct. Few of the references are listed below more references are available in public domain.

Comprehensive 1-MCP research reviews and research bibliographies:

1. Blankenship, S.M. and J.M. Dole, 1-Methylcyclopropene: a review. Postharvest Biology and Technology, 2003. 28(1): p. 1-25.
2. Watkins, C.B., The use of 1-methylcyclopropene (1-MCP) on fruits and vegetables. Biotechnology Advances, 2006. 24(4): p. 389-409.
3. Fan, X., S.M. Blankenship, and J.P. Mattheis, 1-Methylcyclopropene Inhibits Apple Ripening. Journal of the American Society for Horticultural Science, 1999. 124(6): p. 690-695.
4. DeEll, J.R., et al., Influence of temperature and duration of 1-methylcyclopropene (1-MCP) treatment on apple quality. Postharvest Biology and Technology, 2002. 24(3): p. 349-353.
5. Jiang, Y. and D.C. Joyce, 1-Methylcyclopropene treatment effects on intact and fresh-cut apple. Journal of horticultural science & biotechnology, 2002. 77(1): p. 19-21.
6. Watkins, C.B. and J.F. Nock, Effects of Delays between Harvest and 1-Methylcyclopropene Treatment, and Temperature during Treatment, on Ripening of Air-stored and Controlled-atmosphere-stored Apples. HortScience, 2005. 40(7): p. 2096-2101.

Effect of 1-MCP on reducing superficial scald

1. Watkins, C.B., J.F. Nock, and B.D. Whitaker, Responses of early, mid and late season apple cultivars to postharvest application of 1-methylcyclopropene (1-MCP) under air and controlled atmosphere storage conditions. Postharvest Biology and Technology, 2000. 19(1): p. 17-32.
2. Rupasinghe, H., et al., Inhibitory effect of 1-MCP on ripening and superficial scald development in'McIntosh'and'Delicious' apples. Journal of Horticultural Science and Biotechnology, 2000. 75(3): p. 271-276.
3. Zanella, A., Control of apple superficial scald and ripening—a comparison between 1-methylcyclopropene and diphenylamine postharvest treatments, initial low oxygen stress and ultra low oxygen storage. Postharvest Biology and Technology, 2003. 27(1): p. 69-78.
4. Sabban-Amin, R., et al., Low oxygen and 1-MCP pretreatments delay superficial scald development by reducing reactive oxygen species (ROS) accumulation in stored ‘Granny Smith’ apples. Postharvest Biology and Technology, 2011. 62(3): p. 295-304.
5. Zanella, A. Control of apple scald-a comparison between 1-MCP and DPA postharvest treatments, ILOS and ULO storage. in VIII International Controlled Atmosphere Research Conference 600. 2001.
6. Pesis, E., et al., A simple pretreatment with low O2 to alleviate superficial scald in Granny Smith apples. Journal of the Science of Food and Agriculture, 2007. 87(10): p. 1836-1844.

Effect of 1-MCP on volatile production, decay control and nutritional value

1. Fan, X. and J.P. Mattheis, Impact of 1-Methylcyclopropene and Methyl Jasmonate on Apple Volatile Production. Journal of Agricultural and Food Chemistry, 1999. 47(7): p. 2847-2853.
2. Lurie, S., et al., Effect of 1-Methylcyclopropene on Volatile Emission and Aroma in Cv. Anna Apples. Journal of Agricultural and Food Chemistry, 2002. 50(15): p. 4251-4256.

3. Saftner, R.A., et al., Effects of 1-methylcyclopropene and Heat Treatments on Ripening and Postharvest Decay in Golden Delicious' Apples. Journal of the American Society for Horticultural Science, 2003. 128(1): p. 120-127.
4. Fawbush, F., et al., Antioxidant contents and activity in SmartFresh-treated 'Empire' apples during air and controlled atmosphere storage. New York Fruit Quarterly, 2009. Volume 17. Number 4.
5. MacLean, D.D., et al., Postharvest variation in apple (Malus domestica Borkh.) flavonoids following harvest, storage, and 1-MCP treatment. Journal of Agricultural and Food Chemistry, 2006. 54, 870-878.

Need for 1-MCP over current practices

1. Bai, J., et al., Response of Four Apple Cultivars to 1-Methylcyclopropene Treatment and Controlled Atmosphere Storage. HortScience, 2005. 40(5): p. 1534-1538.
2. Zanella, A., et al. Fruit fluorescence response to low oxygen stress: modern storage technologies compared to 1-MCP treatment of apple. V International Postharvest Symposium 682. 2004.
3. Mattheis, J.P., X. Fan, and L.C. Argenta, Interactive responses of Gala apple fruit volatile production to controlled atmosphere storage and chemical inhibition of ethylene action. Journal of Agricultural and Food Chemistry, 2005. 53(11): p. 4510-4516.
4. Prange, R.K., et al., Innovation in controlled atmosphere technology. Stewart Postharvest Review, 2005. 1(3): p. 1-11.
5. Watkins, C.B., Dynamic Controlled Atmosphere Storage –A New Technology for the New York Storage Industry? New York Fruit Quarterly, 2008. 16(1): p. 23-26.
6. Asif, M.H., et al., Effect of low oxygen, temperature and 1-methylcyclopropene on the expression of genes regulating ethylene biosynthesis and perception during ripening in apple. South African Journal of Botany, 2009. 75(1): p. 137-144.
7. McCormick, R., et al., A case study: Potential energy savings using 1-MCP with 'Gala' apples in commercial CA storage. Acta Horticulture, 2010 877: p. 323–326.
8. Weber, A., et al., 'Royal Gala' apple quality stored under ultralow oxygen concentration and low temperature conditions. Pesquisa Agropecuária Brasileira, 2011. 46(12): p. 1597-1602.
9. Anderson, L., Dynamic controlled atmosphere for storage of organic apples. ICROFS news, 2013. P: 10-11.
10. Kittemann, R., et al., Effect of high temperature and 1-MCP application or dynamic controlled atmosphere on energy savings during apple storage. European Journal of Horticultural Science, 2015. 80 (1): p. 33–38.

12. A "Petition Justification Statement" which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

- **Explain why the synthetic substance is necessary for the production or handling of an organic product.**

The primary need for SmartFresh in organic apples is due to its ability to reduce wastage of the fruit by effectively extending and maintaining the fruit quality throughout the storage, distribution and consumption window. SmartFresh, unlike other technologies, not only helps to maintain fruit quality during storage, but also continue to maintain quality of apples outside storage until ready for

consumption, giving the organic farmers peace of mind and ensuring they provide their consumers with a good eating experience long into the marketing season. There is currently no greener technology available, both in terms of its environmental impact based on low energy requirement and human safety based on the extremely low levels used with no residue in apples.

The supply chain for local organic apples suffers a relatively high degree of loss, as reported by many grocers, making the fruit unavailable for consumption. The loss of organic fruit for consumption would not only mean "wastage" of the fruit itself, but wastage in the resource used for production of the fruit, which is relatively high for organic crops. The unavailability of local organic apples would also mean import of overseas organic apples to make organic apples available all through the year.

Presently organic fruit is stored for up to 6 to 8 months in controlled atmosphere (CA) storage. Near the end of that storage period, the organic fruit is known to be of questionable quality. Moreover low oxygen technologies that regulate apple respiration are suitable in maintaining fruit quality only during the storage period. Once the fruit is taken out of storage, there is discernible quality loss due to faster respiration leading to rapid fruit softening, making them unsuitable for consumption and is well recorded. With the use of SmartFresh, the organic marketing of GOOD QUALITY organic apples could be extended, perhaps up to 12 months. As fruit matures it respires, and as a result, it suffers desiccation, which leads to more decay and the fruit softens and becomes unappealing, as well as suffering a loss of nutritional value. Good quality would mean crisp apples, with the desired nutritional quality maintained for the storage, distribution and consumption period.

SmartFresh treatment is also an excellent control of Storage Scald (browning of apple skin). Virtually all the apples grown organically are grown in "desert' climates (fewer pests and mildew issues), and apples grown in warmer climates are more susceptible to storage scald. Also, fruit to be stored longer (sold in June/July/August) is generally the less mature fruit, which has more propensities to develop unmarketable storage blemishes caused by storage scald. Certain varieties like Red Delicious, Granny Smith and Fuji are more susceptible to storage scald and about 40 to 50% of all organically grown apples are these varieties.

Low levels of 1-MCP, in form of SmartFresh are sufficient for providing effective quality maintenance in apples (0.00000086% wt/wt of fruit). It is a gas used in closed room, which can be a container, tent or a full size storage room, and is effective when used at any temperature from 0°C-25°C (32°F-77°F). Fruit exposed to very low levels of SmartFresh can be stored at higher temperatures with similar results in eating quality, thus lowering the energy usage. For example, Gala apples stored with SmartFresh technology at 4°C (39.2°F), used 35% less energy than the control apples stored at the standard temperature of 1.5°C (34.7°F). A sensorial study carried out after storage clearly showed consumers' preference for SmartFresh quality apples.

To quote Modern Farmer, SmartFresh is considered a "great tool" that helps small apple growers store their local apples and make them available in the marketplace longer (*http://modernfarmer.com/2013/08/the-science-of-cold-apple-storage/*).

- **Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.**

  There are no alternate technologies to 1-MCP to maintain the quality of fruit after storage. The current practices described below maintain fruit quality during storage, while 1-MCP is needed to help maintain fruit quality during storage and during entire marketing chain.

  Current practices for fruit storage: "Fruit ripening is a highly regulated process with multiple coordinated events, leading to transform a physiologically mature but inedible fruit into an edible,

tasty product" (Streif, J., Ripening management and postharvest fruit quality. Acta Horticulturae, 2010. 858: p, 121-129). Current technologies such as Dynamic Controlled Atmosphere (DCA) and Ultra Low Oxygen (ULO) function by lowering the metabolic activity of apples during storage but have little to no effect once the fruit leaves the storage area and gets into the distribution cycle.

DCA: They work by continuous monitoring of the ethanol concentration, fruit respiration and/or chlorophyll fluorescence (technology patented under HarvestWatch^{TM}) in apples and lower oxygen levels over time in response to changes in fruit metabolism, in combination with low storage temperatures. They apply low oxygen atmospheres close to the lowest tolerance limits for fruit, below which would trigger anaerobic metabolism. The oxygen concentration is placed at the Anaerobic Concentration Point (<1% oxygen), and the CO_2 levels can go upto 2.5%. Though DCA is designed to detect the low oxygen stress point of the fruit with the onset of anaerobic respiration by measuring fermentation products and chlorophyll fluorescence of fruit, it is not always feasible to make a good estimate of the situation with the amount of fruit stored in the room and the variability that exists.

ULO: It works by lowering the oxygen level to 1% or less during storage as a means to reduce ethylene production and lower metabolic activity in the fruit during storage, along with very low storage temperatures. Fruit stored continuously at lower oxygen levels can accumulate alcoholic off - flavors due to anaerobic respiration.

Pros and Cons of the technologies: The DCA and ULO technologies have shown benefits in protecting the fruit quality during storage, but do not continue the protection once the fruit leaves the storage facility. The quality of the fruit have shown to deteriorate quickly through fruit softening and internal browning, once the fruit is in normal air (O_2: 21%) and the temperature increases in the marketing chain, preventing the consumers from getting a good quality apple. If the fruit quality is not held during marketing it results in wastage of fruit being thrown out and unsuitable for consumption, but also wastage in the energy expended by using the ULO/ DCA for storage of the fruit that gets wasted.

The major advantage of 1-MCP over the current practices is that it not only helps fruit in storage, but also during the entire marketing chain, as it prevents softening and browning of fruit at warmer temperatures. This facilitates the consumers to get a better quality fruit for consumption and also reduces the wastage of fruit. Due to the non-toxic mode of action at very low levels and undetectable residue in fruit, SmartFresh, 1-MCP complexed in alpha-cyclodextrin, is the most preferred solution for apple industry in maintaining fruit quality during storage conditions.

- **Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.**

The petitioned use of SmartFresh 1-MCP for organic apples has a better effect on the environment compared to other current practices which targets reducing fruit respiration by controlling the oxygen levels.

The current practices for apple storage such as DCA and ULO requires utilization of high energy for storage in form of running the refrigeration compressors, ventilation fans, energy required in

constantly monitoring the fruit quality and adjusting the oxygen levels in the room. These technologies, though help in holding fruit well during storage, the intensification in the technologies from CA to ULO to DCA, have also lead to very high energy consumption leading to higher CO_2 footprint. Also, the high probability of quality loss in fruit when moved from the low oxygen environment to normal atmosphere and higher temperatures during distribution leads to tremendous wastage in energy spent to store the fruit.

Work done by Kittemann, R., et al., have shown that the energy was reduced by 70% by combining ULO and 1-MCP at 5°C compared to ULO at 1°C (Effect of high temperature and 1-MCP application or dynamic controlled atmosphere on energy savings during apple storage. European Journal of Horticultural Science, 2015. 80 (1): p. 33–38). Also, very low levels of 1-MCP is sufficient to provide the desired effect in fruit quality and 1-MCP has shown to maintain the fruit quality not only during storage but also during the marketing window. For example, a 1000 cubic feet room containing 7500 Kg of apples would require less than 0.062g of 1-MCP for effective maintenance of apple quality during storage, which is about 0.00000836 g per Kg apples. 1-MCP is thus a very useful tool to help compensate the negative effects due to increased storage temperature, without compromising the fruit quality to a greater extent.

Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

• Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
Not applicable.

• Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
Not applicable.

C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604
• Explain why the non-synthetic substance should not be permitted in the production of an organic product.
Not applicable.

• Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.
Not applicable.

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

• Explain why the non-synthetic substance should be permitted in the production of an organic product.
Not applicable.

• Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other nonsynthetic or synthetic substances on the National List or alternative cultural methods.
Not applicable.

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance onto the National List, § 205.605(a)

• Explain why the substance is necessary for use in organic handling.
Not applicable.

• Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
Not applicable.

• Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.
Not applicable.

F. Removal of a Non-Synthetic, Non-Agricultural Substance from the National List, § 205.605(a)

• Explain why the substance is no longer necessary for use in organic handling.
Not applicable.

• Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.
Not applicable.

G. Inclusion of a Non-Organically Produced Agricultural Substance onto the National List, § 205.606

• Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.
Not applicable.

• Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the appropriate form, appropriate quality, and appropriate quantity to fulfill an essential function in a system of organic handling.
Not applicable.

• Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria: (1) Regions of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and (5) Other issues which may present a challenge to a consistent supply.
Not applicable.

H. Removal of a Non-Organically Produced Agricultural Substance from the National List, § 205.606

• Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.

Not applicable.

• Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the appropriate form, appropriate quality, and appropriate quantity to fulfill an essential function in a system of organic handling.
Not applicable.

• Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria: (1) Region of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and; (5) Any other issues which may present a challenge to a consistent supply.
Not applicable.

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim. (b) ''Trade secrets'' (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy. (c) Each page containing CBI material must have ''CBI Copy'' marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and ''CBI.'' (d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI deleted copy is paginated the same as the CBI copy (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI). Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy. (e) Each page with CBI deletions should be marked ''CBI-deleted'' at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ''CBI-deleted.'' (f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ''pages 7 through 10 have been CBI-deleted.'') (g) All published references that appear in the CBI copy should be included in the reference list of the CBI deleted copy. Published information cannot be claimed as confidential.

Not applicable.

1-Methylcyclopropene (1-MCP) - Tolerance Requirement Exemption 7/02

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-2002-0142; FRL-7187-4]
1-Methylcyclopropene; Exemption from the Requirement of a Tolerance
AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 1-Methylcyclopropene (1-MCP) in or on fruits and vegetables when used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene. AgroFresh, Inc. (formerly BioTechologies for Horticulture) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1-MCP.
DATES: This regulation is effective July 26, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0142, must be received on or before September 24, 2002.
ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0142 in the subject line on the first page of your response.
FOR FURTHER INFORMATION CONTACT: By mail: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9525; e-mail address: Benmhend.driss@epa.gov.

SUPPLEMENTARY INFORMATION:
I. General Information
A. Does this Action Apply to Me?
You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this

action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html.

2. In person. The Agency has established an official record for this action under docket ID number OPP-2002-0142. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the Federal Register of June 21, 2000 (65 FR 38550) (FRL-6589-5), EPA issued a notice pursuant to section 408(d)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d)(3), as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP OF6144) by AgroFrech, Inc. (formerly BioTechnologies for Horticulture, Inc.), 100 Independence Mall West, Philadelphia, PA 19106-2399. As required by section 408(d)(2)(A)(i)(I), this notice included a summary of the petition prepared by the petitioner AgroFresh, Inc. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The end-use product, a white powder, when mixed with water or a buffer solution releases the gas 1-MCP. The active ingredient acts an inhibitor to ethylene, by blocking the attachment of ethylene to tissue, and thus, prolongs the life of the food commodity treated.

Toxicity studies submitted in support of the tolerance exemption petition, and the Agency reviews are compiled in the official record established for this action under the docket ID number OPP-2002-0142.

1. Acute toxicity (MRIDs 444647-04 to 08). 1-MCP exhibits low acute toxicity. It is a category IV biopesticide. The rat oral LD50 is greater than 5,000 milligrams/kilograms (mg/kg), the rabbit dermal LD50 is greater than 2,000 mg/kg and the rat inhalation LC50 is greater than 2.5 milligram/liter (mg/L) (or greater than 1,126 parts per million (ppm) v/v active ingredient in air). No deaths or clinical signs of systemic toxicity were observed following these acute exposures. 1-MCP produces minimal irritation of skin and eyes in rabbits and 1-MCP is not a skin sensitizer. No hypersensitivity incidents were observed following exposure to 1-MCP.

2. Genotoxicity (MRID 444647-09). 1-MCP was not mutagenic when tested as a gas in several short-term in vitro/in vivo assays, including a bacterial reverse mutation assay (Ames test), an in vitro mammalian point mutation assay in Chinese hamster ovary cells, an in vitro cytogenetics assay in human lymphocytes and an in vivo mouse micronucleus assay following inhalation exposure. In addition, 1-MCP is not mutagenic when tested as a suspension in cell media in the Ames test and in the in vitro mouse lymphoma forward mutation assay (MRID 444647-10) and is not mutagenic in the in vivo mouse micronucleus assay (MRID 444747-11) following oral exposure (gavage).

3. Developmental toxicity (MRID 454586-08). 1-MCP produces no developmental toxicity when tested in a standard developmental toxicity study in the rat via inhalation at concentrations up to and including 2.3 mg a.i./L (or 543 mg a.i./kg/day, 6 hr exposure/day). The no observed adverse effect level (NOAEL) for maternal toxicity was 0.24 mg a.i./L (56 mg a.i./kg/day, 6 hr exposure/day).

4. Subchronic toxicity (MRID 456090-01). 1-MCP was tested in a 90-day inhalation study at doses of 0.05, 0.24 and 2.3 mg a.i./kg in the rat. The NOAEL is 0.05 mg a.i./L (equivalent to 9 to 15 mg a.i./kg/day), based on minimal to mild effects on spleen and kidney histopathology at 0.24 mg a.i./L (equivalent to 39 to 66 mg a.i./kg/day). In this study there was no evidence of neurotoxicity, no effects on the respiratory tract and no effects on pathology of any endocrine or reproductive organs up to and including the highest dose tested of 2.3 mg a.i./L (or equivalent to 380 to 640 mg a.i./kg/day).

5. AgroFresh (the applicant) submitted a waiver request for the immune response data requirements based on the current toxicological data submitted on 1-MCP. The review of the 3-month inhalation rat study

(mentioned in the previous paragraph) indicates, no effects on thymus weight and no effects on the histopathology of the thymus, bone marrow or spleen that would be attributed to an impact on the immune system were seen. There were no effects on white blood cell differential parameters (including monocytes, lymphocytes, segmented neutrophils or eosinophils) and no basophils were observed which may be indicative of an allergic reaction. The Agency concluded that 1-MCP did not induce dysfunction or inappropriate suppressive responses in components of the immune system. As a result, immune response data requirements were waived.

6. Other. 1-MCP has a mode of action in plants which is a non-persistent and non-toxic mode of action. 1-MCP prevents the natural chemical, ethylene, from binding to ethylene receptors in plants. This mode of action is not relevant in animals, since ethylene receptors are not present in animal tissues.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. 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, avocadoes, mangoes, papayas, kiwifruit, plums, apricots and persimmons. Studies submitted (MRID 456090-02) 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-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.

2. 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.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to 1-MCP for the general population, is unlikely because potential use sites are commercial, agricultural, and horticultural. 1-MCP is currently registered for indoor, nonfood commercial use on flowers and ornamentals. The Agency has approved that use, based on the data submitted that show little potential for significant non-occupational exposure to the general population.

1. Dermal exposure. 1-MCP will only be sold enclosed in a generator for treatment of raw agricultural commodities. The generator will not release 1-MCP until the applicator has exited the storage area and entrances to the treatment area have been sealed. At the end of the treatment period, the storage area will be vented before workers are permitted to reenter the area. This label mitigating language would eliminate the potential for dermal exposure to handlers

or applicators.

2. Inhalation exposure. As mentioned in the previous paragraph, the use of this product according to the label instructions would result in little, if any, inhalation exposure to handlers or applicators.

V. Cumulative Effects

The Agency has considered the cumulative effects of 1-MCP and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. There is no indication of mammalian toxicity at the maximum doses tested, of this or other products containing 1-MCP.

VI. Determination of Safety for U.S. Population, Infants and Children

1. U.S. population. 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.

2. Infants and children. 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-MCP residues. Exemption of 1-MCP from the requirements of a tolerance should pose no significant risk to humans or the environment

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen- and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program(EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, 1-MCP may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of 1-MCP. In addition, 1-MCP does not share any structural similarity to any known endocrine disruptive

chemical.

B. Analytical Method(s)

EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including 1-MCP's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for 1-MCP.

C. Codex Maximum Residue Level

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.

VIII. Conclusions

Based on the toxicology data submitted, there is reasonable certainty no harm will result from aggregate exposure of residues of 1-MCP to the U.S. population, including infants and children, when the proposed product is used in accordance with label instructions and good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which reliable data were submitted, accepted and reviewed. The Agency has arrived at this conclusion based on the data submitted demonstrating no toxicity at the maximum doses tested. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of 1-MCP in or on all food commodities.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0142 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 24, 2002.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900),

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0142, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355,

May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications " as described in Executive Order 13175, entitled Consultation and Coordination with
Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 16, 2002.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.1220 is added to subpart D to read as follows:

Sec. 180.1220 1-Methylcyclopropene; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of 1-Methylcyclopropene in or on fruits and vegetables when used as a post harvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene.

[FR Doc. 02-18868 Filed 7-25-02; 8:45am]

BIOPESTICIDE REGISTRATION ACTION DOCUMENT

1- Methylcyclopropene
(PC Code 224459)

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

Table of Contents

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment
2. Environmental Fate and Ground Water Data
3. Ecological Exposure and Risk Characterization

D. EFFICACY DATA

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

B. REGULATORY POSITION

1. Conditional/Unconditional Registration
2. CODEX Harmonization
3. Nonfood Re/Registrations
4. Risk Mitigation
5. Endangered Species Statement

C. LABELING RATIONALE

1. Human Health Hazard
   a. Worker Protection Standard
   b. Non-Worker Protection Standard
   c. Precautionary Labeling
   d. Spray Drift Advisory
2. Environmental Hazards Labeling
   End-Use Product Environmental Hazards Labeling
3. Application Rate

D. LABELING

V. Actions Required by Registrants

VI. Appendix A

I. Executive Summary

A. IDENTITY

Under normal environmental conditions, the active ingredient methylcyclopropene (1-MCP) 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 negligeable. 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

Chemical Formula: $C_{10}H_{18}O$

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 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 $C_{10}H_{18}O$. 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 ºC ; color changes from white to brown at 260 ºC.	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	
151B-17(I)	pH	3.92 (in a 5.02% aqueous solution	445676-01

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
151B-17(j)	Stability	Stable between 0 and 37 ºC, 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 LD_{50} 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 LD_{50} was >2000 mg/kg; tox category III. Based on a lack of mortality observed in albino rats exposed to165 ppm of 1-MCP gas for 4 hours, the LC_{50} 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 - *Salmonella typhimurium* gene mutation assay	Not mutagenic	444647-09
152-18	Cellular immune response	Waived	
152-19	Mutagenicity: * Mouse Lymphoma forward mutation * *In vivo* 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

EPA is required under the FFDCA as amended by FQPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ``may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen- and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program(EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, 1-MCP may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of 1-MCP. In addition, 1-MCP does not share any structural similarity to any known endocrine disruptive chemical.The Agency is not requiring information on the endocrine effects of this compound at this time.

2. Dose Response Assessment

No toxicological endpoints are identified.

3. Dietary Exposure and Risk Characterization

1. 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, avocadoes, mangoes, papayas, kiwifruit, plums, apricots and persimmons. Studies submitted (MRID 456090-02) 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-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.

2. 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.

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

1. U.S. population. 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.

2. Infants and children. 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-MCP residues.

6. 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.

7. Cumulative Effects

The Agency has considered the cumulative effects of 1-MCP and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. There is no indication of mammalian toxicity at the maximum doses tested, of this or other products containing 1-MCP.

8. 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. 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 55ºF, 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 35º and 55ºF, 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® Use Sites Fresh cut flowers and potted flowering, bedding, nursery and foliage plants.	Official date registered: April 22, 1999

SmartFresh™ Technology Use Sites Post-harvest Fruits (apples, melons, tomatoes, pears, avocadoes, mangoes, papayas, kiwifruit, plums, apricots and persimmons	Official date registered: July 17, 2002
SmartFresh™ SmartTabs Use Sites food commodities derived from: apples, melons, tomatoes, pears, avocadoes, 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 Use Sites Fresh cut flowers and potted flowering and foliage plants.	Official date registered: February 3, 2006

FAO SPECIFICATIONS AND EVALUATIONS
FOR AGRICULTURAL PESTICIDES

1-Methylcyclopropene

FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

TABLE OF CONTENTS

1-METHYLCYCLOPROPENE

DISCLAIMER[1]

FAO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

[1] This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural pesticides, with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

Since 1999 the development of FAO specifications follows the **New Procedure**, described in the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products" (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

PART ONE: **The Specification** of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products".

PART TWO: **The Evaluation Report(s)** of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1 or 2 of the "Manual on the development and use of FAO specifications for plant protection products" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

*NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT
http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/

OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

SPECIFICATIONS FOR 1-METHYLCYCLOPROPENE

1-METHYLCYCLOPROPENE

INFORMATION

ISO common name

No ISO common name was allocated for 1-methylcyclopropene

Chemical name(s)

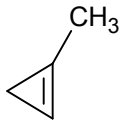
IUPAC 1-methylcyclopropene

CAS 1-methylcyclopropene

Synonyms

1-MCP

Structural formula



Molecular formula

C_4H_6

Relative molecular mass

54.091 g/mol

CAS Registry number

3100-04-7

CIPAC number

767

Identity tests

Retention time in GC, mass spectrum from GC/MS.

1-METHYLCYCLOPROPENE TECHNICAL CONCENTRATE

FAO specification 767/TK (January 2010*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (767/2008). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (767/2008) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of 1-methylcyclopropene at a concentration of 3.3% together with related manufacturing impurities, in the form of a complex with alpha-cyclodextrin, together with any other necessary co-formulants. It shall be in the form of a powder free from visible extraneous matter and added modifying agents except for the diluents.

2 Active ingredient

2.1 **Identity tests** (767/TK/ Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **1-methylcyclopropene content** (767/TK Note 1)

The 1-methylcyclopropene content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerance:

Declared content, g/kg	Tolerance
up to 33 Note: the upper limit is included in the range	± 10% of the declared content

3 Relevant impurities

3.1 **By-products of manufacture (Note 2)**

Maximum 0.05% of 3-chloro-2-methylpropene of the 1- MCP content found under 2.2.

Maximum 0.05% of 1-chloro-2-methylpropene of the 1-MCP content found under 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

Note 1 Methods for the identification and determination of 1-MCP content in TK and in a VP formulation were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC methods. Prior to their publication in Handbook N, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm

Note 2 The independent laboratory validated capillary GC-FID method (CIPAC/4667) for the determination of the relevant impurities 3-chloro-2-methylpropene and 1-chloro-2-methylpropene in 1-MCP TK and VP formulation was adopted by CIPAC in 2009 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

1-METHYLCYCLOPROPENE VAPOUR RELEASING PRODUCT

FAO specification 767/VP (January 2010*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (767/2008). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (767/2008) as PART TWO forms an integral part of this publication.

1 Description

The material is identical to 767/TK It shall be in the form of a powder to be applied as a gas of the active ingredient after dissolution in water, but which may contain insoluble inert ingredients.

2 Active ingredient

2.1 **Identity tests** (767/VP/ Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **1-methylcyclopropene content** (767/VP/ Note 1)

The 1-methylcyclopropene content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerance:

Declared content, g/kg	Tolerance
up to 33 Note: the upper limit is included in the range	± 10% of the declared content

3. Relevant impurities (Note 2)

3.1 By-products of manufacture

Maximum 0.05% of 3-chloro-2-methylpropene of the 1- MCP content found under 2.2.

Maximum 0.05% of 1-chloro-2-methylpropene of the 1-MCP content found under 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

4 Storage stability

4.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage.

Note 1 Methods for the identification and determination of 1-MCP content in TK and in a VP formulation were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC methods. Prior to their publication in Handbook N, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm

Note 2 The independent laboratory validated capillary GC-FID method (CIPAC/4667) for the determination of the relevant impurities 3-chloro-2-methylpropene and 1-chloro-2-methylpropene in 1-MCP TK and VP formulation was adopted by CIPAC in 2009 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm

PART TWO

EVALUATION REPORTS

1-METHYLCYCLOPROPENE

FAO/WHO EVALUATION REPORTS 767/2008

Recommendations

The Meeting recommended that:

(i) the specifications for 1-methylcyclopropene (1-MCP), TK and VP proposed by Rohm and Haas, as amended, should be adopted by FAO

Appraisal

1-MCP is an active ingredient that is under patent and has not previously been the subject of FAO specifications. The proposer stated that 1-MCP is prepared and traded only as the TK which is also the end use product, the VP. 1-MCP is used at ppm levels in storage rooms mainly for apples to control ethylene-induced ripening processes and is therefore considered as a plant growth regulator.
1-MCP is a gas at room temperature and standard pressure. The solubility in water is 137 mg/L at 20 ˚C. 1-MCP is slightly fat soluble (log P_{ow} = 2.4) and is soluble in some organic solvents. The auto flammability was in the range of 188-191°C and the lower flammability level around 1.25-1.60 %. The in-use concentration range will therefore never exceed levels of concern with regard to flammability.

1-MCP is commercialised as an inclusion complex with alpha-cyclodextrin, which has been shown not to be highly flammable. The active substance cannot be isolated in a purified form as it rapidly self-reacts resulting in a violent exothermic reaction.

Confidential information on the manufacturing process, on impurities at or above 1 g/kg in 1-MCP, and on toxicological relevant impurities, was provided by the proposer. On the basis of the information provided impurities 3-chloro-2-methylpropene and 1-chloro-2-methylpropene have to be regarded as relevant impurities. The limits proposed, 0.05%, were below the classification and labelling limits of GHS for carcinogenic and mutagenic impurities (0.1%), and thus in line with earlier JMPS recommendations. The limits for the impurities were supported by 5 batch analyses. Mass balances were high (99-100%). Confirmation was received from the UK Pesticides Safety Directorate that the information on the batch analysis and manufacturing process were the same as those submitted for registration in the UK. The data supplied supports the minimum specification for the active ingredient.

The analytical method for determination of 1-MCP in the formulation is based on capillary GC with FID on a Porabond column providing sufficient retention of the target compound, similar to those for the relevant impurities 1- and 2-chloromethylcyclopropene.

There is a reduced data set available for this active because of the nature of the compound, its indoor use and exposure routes connected to that specific use. There is limited ecotoxicity data as there will be very limited exposure. This reduced data set

was accepted by the EU. A reasoned case for the non-submission of this data was also provided by the data holder.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 767/2008

Uses

1-MCP is a plant growth regulator for food storage, predominantly for apples. It blocks the ethylene receptors, preventing normal fruit responses to ethylene. The product is manufactured as a TK, which is also the end use product. The 1-MCP gas is released from the TK into the controlled atmosphere by dissolving it in water: The water molecules displace the 1-MCP in the alpha-cyclodextrin inclusion complex.

Identity of the active ingredient

ISO common name

No ISO common name was allocated for 1-methylcyclopropene

Chemical name(s)

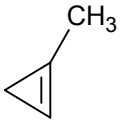
IUPAC 1-methylcyclopropene

CAS 1-methylcyclopropene

Synonyms

1-MCP

Structural formula



Molecular formula

C_4H_6

Relative molecular mass

54.091 g/mol

CAS Registry number

3100-04-7

CIPAC number

767

Identity tests

Retention time in GC, mass spectrum from GC/MS.

Physico-chemical properties of 1-MCP

Table1. Physical-chemical properties of 1-MCP[1]

Parameter	Value(s) and conditions	Method	References
Vapour pressure	$2x10^{5}$ Pa at 20 °C of 1-MCP gas	Modified Watson correlation	AF-01-190 ER 7.21
Melting point	Not relevant as 1-MCP is a gas	OECD 102	AF-01-155 ER 7.15
Boiling point	Not relevant as 1-MCP will instantly polymerise	OECD 103 Meissner's calculation	AF-01-156 ER 7.16
Temperature of decomposition	The formulated product was stable up to 150 ^{o}C	1-MCP could not be tested due to the extreme hazards associated with handling neat 1-MCP OECD 113	
Solubility in water	solubility at 20°C was 137 mg/L No pH effect	Moderately soluble. The method involved the production of gas from the product which was then bubbled through water until saturation was reached. OECD 105 and EEC A.6.	AF-01-191 ER 8.5
Solubility in organic solvents	solvent solubility (mg/L) n-heptane 2450 xylene 2250 ethyl acetate 12500 methanol 11000 acetone 2400 dichloromethane 2000	Moderately soluble. The method involved the production of gas from the product which was then bubbled through each solvent until saturation was reached.	AF-01-189 ER 8.3
Octanol/water partition coefficient	log P_{ow} = 2.4	EEC method A 8 HPLC OECD 107 and 117	APR-01-014 ER 7.8

Hydrolysis (DT_{50}) characteristics	Not relevant. 1-MCP will not hydrolyse.	OECD 111	AF-01-188 ER 8.2
Flammability	LFL: 1.25-1.60 % The in use concentration will never exceed levels of concern. Auto flammability: 188-191 °C	ASTM method E681, 1985 ASTM method E659, 1984 (1)	AF-01-153 ER 7.13
Photolysis characteristics	Not required since no absorption max in aqueous solution > 240 nm		
Other degradation characteristics Stability in air, photochemical oxidative degradation.	Reaction with hydroxyl radical measured to give a calculated half life of 4.4 hours in the atmosphere.	Laser induced	00RC-1033 ER 6.2 APR-01-054 ER 6.11 AF-01-160 ER 7.19
Dissociation characteristics	Not applicable. 1-MCP is an unsaturated aliphatic hydrocarbon and it does not contain functional groups capable of dissociation in water		

[1] All tests were conducted on 1-MCP gas evolved from the inclusion complex with alpha-cyclodextrin

Table 2. **Chemical composition and properties of 1-MCP technical material (TK)**

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99 %
Declared minimum 1-MCP content	960 g/kg based on evolved gas
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities **<** 1 g/kg and maximum limits for them:	3-chloro-2-methylpropene ≤0.05 % of the evolved gas 1-chloro-2-methylpropene ≤0.05 % of the evolved gas
Stabilisers or other additives and maximum limits for them:	Alpha-cyclodextrin encapsulation agent and dextrose. The dextrose is used as a diluent to adjust the content of 1-MCP in the TK to 3.3%.
Melting or boiling temperature range of the TK	Not applicable as the TK is an alpha-cyclodextrin complex.

Background information on toxicology / ecotoxicology

1-MCP has been reviewed for classification by European Chemicals Bureau (ECB) on November, 2006 and January, 2007. ECB has concluded that no health classification is needed for 1-MCP up to a maximum concentration of 5.0% in alpha-cyclodextrin. Also, ECB concluded no classification would be required for environmental effects. A minimum data set on ecotoxicity is necessary for this compound as it is only used indoors and environmental exposure is very low.

Formulations and co-formulated active ingredients

1-MCP is manufactured and encapsulated into alpha-cyclodextrin as an inclusion complex in a single manufacturing process. The resulting material is then filtered, washed and dried to a powder and the concentration of 1-MCP is adjusted to 3.3 % by the addition of dextrose. 1-MCP is not co-formulated with any other pesticide. The only formulation type is the VP.

Methods of analysis and testing

1-MCP is determined by gas chromatography (GC), using a surrogate calibration standard, cis-2-butene and FID detection. Identification is by means of GC retention time. Validation included running specially isolated pure 1-methylcyclopropene against

cis-2-butene demonstrating that the detector response was within 5 % and the test method corrects for the difference. A batch was also analysed by GC-MS, which supported the structural identity of 1-MCP. The method of the relevant impurities is by GC-FID. The calibration is against analytical standards of each compound. Structural identity of impurities was confirmed by GC-MS. As the TK and formulated product are the same, no additional method was provided. These methods were adopted by CIPAC in 2009.

Physical properties

Test methods for determination of physico-chemical properties were EC, OECD, CIPAC and USEPA. The physical properties and the methods for testing them, and the limits proposed for the TK/VP, comply with the requirements of the FAO and WHO Manual (March 2006 edition).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient content is expressed as 1-MCP in g/kg for the VP formulation.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

The proposer confirmed the toxicological data included in the summary below were derived from 1-MCP having impurity profiles similar to those referred to in the table above.

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 3. Toxicology profile of 1-MCP technical material, based on acute toxicity, irritation and sensitization.

Species	**Test**	**Duration and conditions or guideline adopted**	**Results and test form of 1-MCP**	References
Rat	Oral	No study	n.a.	n.a.
Rabbit	Dermal	No study	n.a.	n.a.
Rat Sprague-Dawley	Inhalation OECD 403	4 hour nose only	LC50≥2.5 mg/L concentration maximum	00R-180A ER4.1
Rabbit	Skin irritation	No study	n.a.	n.a.
Rabbit	Eye irritation	No study	n.a	n.a.
Guinea pig	Skin sensitisation	No study	n.a.	n.a.

Oral and dermal studies in rats:

Based on the physical nature of 1-MCP (i.e. a gas at room temperature), this active substance was not tested in oral or dermal toxicity studies. However, the active substance was tested via inhalation toxicity tests, inhalation being a pertinent route of potential human exposure, although virtually no exposure is expected from normal use.

No practical potential for oral exposure is expected. Using worst-case assumptions, dietary intake will be <<0.2 µg/kg bw/day. Because there is no practical exposure for operators or consumers, a limited data package was considered acceptable and hence only one species has been used in the short-term toxicity tests.

Table 4 Toxicological profile of 1-MCP based on repeated administration.

Species	**Study** **Batch**	**NOAEL** **(mg/kg bw)**	**LOAEL** **(mg/kg bw)**	**Effect at LOAEL** **(and other comments)**	**References**
Rat Sprague-Dawley	2-week inhalation toxicity study in female rats	62 average 92 a.t.d. (105 ppm)	183 average 284 a.t.d. (306 ppm)	Increased incidence of splenic extramedullary haematopoiesis (red pulp). Decreased RBC at highest dose (1000 ppm)	00R-183A ER3.2
Rat Sprague-Dawley	3-week inhalation toxicity study in male rats	42 average 68 a.t.d (107 ppm)	409 average 660 a.t.d (1039 ppm)	Increased incidence of hyaline droplets in the renal cortical tubular epithelium.	00R-183B ER4.3
Rat Sprague-Dawley	90 day inhalation toxicity study in rats	6.5 average 9.0 a.t.d. (23.5 ppm)	28 average 39 a.t.d. (107ppm)	Increased incidence of hyaline droplets in the renal cortical tubular epithelium and splenic haemosiderosis in males. Decreased RBC at highest dose (1000 ppm)	00R-183 ER5.2

Average = dose averaged over the whole study period.

a.t.d. = dose on actual treatment days.

Table 5 Summary of genotoxicity of 1-MCP vapour released from 1 MCP alpha-cyclodextrin complex.

Study	**Test system**	**Result**	**References**
Ames test	*Salmonella typimurium* strains TA98, TA100, TA1535, TA1537,	Negative	00R-193A ER 2.8

	TA102		
In Vitro Cytogenetic Assay	Chromosome aberrations in cultured human peripheral lymphocytes	Negative	00RC-194 ER 3.1
Mammalian Point Mutation	Chinese hamster ovary cells; HGPRT locus	Negative	00RC-195 ER 3.3
In vivo Cytogenetic Assay	Micronucleus assay in mice	Negative	00R-232 ER 2.2

Table 6 Summary of effects in rats administered 1-MCP via inhalation in the teratology study.

ppm 1-MCP		0	107	329	1029
Equivalent body burden on actual days of exposure (mg/kg bw)		0	56	174	543
Number of pregnant dams		n=22	n=20	n=22	n=22
		Maternal body weight gain (g)			
Day 6 to 9		16.9	14.3	15.6	7.4*
Day 9 to 12		17.2	17.9	18.0	20.7*
Day 6 to 20		119.3	117.2	118.4	106.0
		Net maternal body weight change(= Terminal body weight minus day 6 body weight)			
Net Body Weight Change (x)		119.3	117.2	118.4	106.0
Gravid Uterine Weight (y)		75.7	78.6	72.5	72.2
Net Weight Change (x-y)		43.6	38.7	45.8	33.8 *
		Food consumption during gestation			
Day 6 to 9		22.2	23.1	21.7	17.0*
Day 6 to 20		24.1	24.1	25.0	23.1
		Maternal necropsy observations			
Number necropsied No remarkable observations	n n	22 22	22 22	22 17	22 0
Spleen					
Darkened	n %	0 0.0	0 0.0	5 22.7	22 * 100.0
Enlarged	n %	0 0.0	0 0.0	2 9.1	19+ 86.4

		Caesarean section data			
Preimplantation loss	Total	24	22	19	52
Number per animal	Mean	1.1	1.1	0.9	2.5*
% per animal	Mean	7.4	7.3	7.2	15.6a
total live litter sizes	%	12.5	12.6	11.6	12.0

[a] Excludes data from animal #00-02386 that had 'erroneous' corpora lutea counts. The number of implants in this animal (14) were excluded from preimplantation loss calculations.

- * $p < 0.05$ Fisher's exact test with Bonferroni correction. * $p<0.05$ Dunnett's test. + n=21

In an inhalation toxicokinetics study in the rat, 1-MCP appeared rapidly in the blood stream when inhaled. Following exposure, 1-MCP is cleared from the blood compartment at a modest rate. Less than 10% of available radioactivity was absorbed during 4 hours of exposure. At high dose (1000 ppm) exhalation was the main route of excretion. At low dose (100 ppm) urinary excretion and excretion via exhaled air were of equal prominence. Excretion via exhaled air is likely to be irrelevant at proposed in-use atmospheric concentrations. Fecal excretion was a minor route of excretion. Inhalation absorption (akin to oral absorption) of 1-MCP was calculated to be approximately 10%. Bioaccumulation is not expected.

With respect to acute toxicology, due to practical reasons (i.e. 1-MCP being a gas at room temperature) 1-MCP gas was only tested in an acute inhalation study. From the results of this study and from the lack of clinical signs of toxicity in this and the short-term inhalation toxicity studies (where whole body exposures were conducted), it is proposed that 1-MCP gas is unclassified with respect to acute effects.
In the short-term toxicity studies, repeated inhalation of 1-MCP resulted in decreased red blood cells, decreased red blood cell (RBC) parameters, and spleen effects. Other target organs of 1-MCP toxicity were the liver and kidneys. The overall population of white blood cells (WBCs) in males appeared to be increased in treated animals at the highest concentration used. The NOAELs were based on the kidney and RBC effects in all short-term studies.
In vitro and in vivo assays provided no evidence of mutagenic activity for vapour concentrations of 1-MCP up to 1000 ppm.
There is no expected carcinogenic risk from 1-MCP, and no effects of chronic exposure are anticipated when 1-MCP is used according to the product label. 1-MCP was not tested in chronic (long-term) and carcinogenicity studies in the rat and mouse, because there is no potential for chronic, lifetime exposure of man. The 90 day inhalation study in rats raised no alarms for potential effects upon chronic lifetime exposure. There is also no evidence for carcinogenicity or genotoxicity for 1-MCP predicted by structure activity analysis.

A two generation study in the rat was not conducted, since there is no potential for long-term exposure over a significant portion of the human lifespan. Also, in an inhalation developmental toxicity study in the rat, there

were also no adverse reproductive or developmental effects in animals when exposed to concentrations at 1000 times the level of use. Because there is no exposure for operators or consumers, a limited data package was considered acceptable and hence only 1 species has been used in the teratology studies. In the rat teratology study, a maternal NOAEL was set on darkened and enlarged spleens. No adverse fetotoxic effects were observed. The NOAEL for maternal effects for 1-MCP, when administered as a gas via whole-body inhalation over gestational day 6-19 in this developmental study was 107 ppm or 56 mg/kg/day based on darkened and enlarged spleens.

The NOEL for fetotoxicity for 1-MCP, when administered as a gas via whole-body inhalation over gestational day 6-19 in this developmental study was 1029 ppm or 543 mg/kg/day which was the highest dose tested.

Information was considered (DNA and protein sequences comparisons, and comparative ethylene binding assays) which indicated that the ethylene receptor as found in apples and many other plants and non animal kingdom organisms, does not occur in the animal kingdom. Therefore, the mechanism for the binding of ethylene in plants, which produces a sequence of biochemical events, is not relevant to man. Since 1-MCP is known to bind to the same active site in plants as does ethylene, no binding of 1-MCP to receptors in man would be expected as well.
The applicant stated that in the United States no adverse effects have been reported by manufacturing workers, applicators, retailers or the general population. No clinical signs or symptoms of poisoning are anticipated by the applicant to result from human exposure. Apart from basic supportive first aid measures, the applicant also considers that no medical treatment is required. Ultimately the applicant does not expect poisonings to occur through use of this material.

Table 7: Summary of the acute toxicity of 1-MCP cyclodextrin complex.

Route/Study	Test material	Species	Comments	Classification	References
Oral	1-MCP α-cyclodextrin complex	Rat	LD50 >5000 mg/kg bw	Not classified	00R-199 ER2.4
Dermal	1-MCP α-cyclodextrin complex	Rat	LD50 >5000 mg/kg bw	Not classified	00R-200 ER2.5
Skin irritation	1-MCP α-cyclodextrin complex	Rabbit	Not classified.	Not classified	00R-201 ER2.6
Eye irritation	1-MCP α-cyclodextrin complex	Rabbit	Not classified.	Not classified	00R-202 ER2.7
Skin sensitisation M&K method	1-MCP α-cyclodextrin complex	Guinea pig	Not classified.	Not classified	00R-203 ER2.3

No classification for the formulation was required:
No health classification for 1-MCP, up to maximum mass content of 5% encapsulated in cyclodextrin, was recommended by the Technical Committee on Classification and Labelling of ECB (Arona meeting, November 14-15, 2006). Similarly, no classification for environmental effects was recommended for 1-MCP by the Technical Committee on Classification and Labeling of ECB (Ispra meeting, January 25, 2007)

Technical specification and impurities

There are two impurities (Impurity 1, Impurity 2,) present in the technical 1-MCP which are of possible toxicological significance.

Impurity 1 and Impurity 2

Impurity 1 and Impurity 2 are monohaloalkene isomers.

Impurity 1, according to IARC monographs was positive in a heritable translocation assay in Drosophila melanogaster, a sex-linked recessive lethal mutation assay also in D. melanogaster, an in vitro mammalian cell mutation assay at the thymidine kinase locus in L5178Y mouse lymphoma cells in the absence of metabolic activation, and in an in vitro sister chromatid exchange assay in CHO cells. It was negative in 9/10 Ames tests, which were conducted. No in vivo genotoxicity assays were performed in mammals however, it was also carcinogenic in mice and rats.

Impurity 2, according to IARC Monographs was positive in 4/6 Ames assays, a ‘genetic crossing over’ or recombination assay in D. melanogaster, in an in vitro sister chromatid exchange in CHO cells, chromosomal aberration assay

also in CHO cells. Impurity 2 did not induce micronuclei in bone marrow cells in an in vivo assay in mammals (mouse micronucleus test). It was also carcinogenic in mice and rats.

The applicant states that experiments (Snyder 2001) indicate that 99.9% of Impurity 2 and Impurity 1 are released during generation of the active substance from the 3.3% alpha-cyclodextrin complex. These impurities were present at concentrations typical of commercial product in the gas phase in genotoxicity studies with 1-MCP vapour which showed no evidence for mutagenicity of 1-MCP technical.

Impurity 3, Impurity 4 and Impurity 5

These impurities appear to have no structural alerts for potential DNA reactivity according to the model of Ashby and Tennant (1988, Mutation Research 204, 17-115).

Addressing the toxicological significance of Impurity 1 and Impurity 2

The risk of mutagenicity/carcinogenicity presented by these materials was addressed by the Committee for Carcinogenicity in the UK. They concluded that the risk for carcinogenicity posed by exposure to Impurity 1 and Impurity 2 for both workers and consumers was negligible based on the upper limit set for these materials in 1-MCP. That upper limit has since been lowered by an additional 38%. This conclusion was subsequently accepted by EFSA in the EU. Upper limits for these two impurities have been included in the Annex 1 listing of 1-MCP.

ANNEX 2
REFERENCES

Rohm and Haas document number or other reference	Year and title of report or publication details
FAO/WHO 2006	Manual on development and use of FAO and WHO specifications for pesticides, March 2006 revision of the 1st edition. FAO, Rome, March 2006; WHO, Geneva, March 2006 (internet publications).
AF-01-155 ER 7.15	2002. Determination of the melting point/melting range of 1-MCP
AF-01-156 ER 7.16	2002. Determination of the boiling point/boiling range of 1-MCP
AF-01-160 ER 7.19	2002. Screening of the thermal stability in air of 1-MCP
AF-01-190 ER 7.21	2002. Determination of the vapour pressure of 1-MCP
AF-01-157 ER 7.17	2002. Determination of colour and physical state of 1-MCP
AF-01-158 ER 7.18	2002. Determination of odour of 1-MCP
AF-01-187 ER 8.1	2002. Determination of the density of 1-MCP
AF-01-191 ER 8.5	2002. Determination of the water solubility of 1-MCP
AF-01-189 ER 8.3	2002. Determination of the solubility of 1-MCP in organic solvents
APR-01-014 ER 7.8	2001. Determination of the partition coefficient (n-octanol/water) of 1-MCP formulation
AF-01-188 ER 8.2	2002. Hydrolysis determination of 1-MCP at different pH values
AF-01-153 ER 7.13	2002. Determination of the flammability of 1-MCP formulation
APR-01-054 ER 6.11	2001. Estimation of the degradation of 1-MCP by photo-oxidation in air
00RC-1033 ER 6.2	2000. Process safety test results and interpretation for 1-methylcyclopropene
APR-00-213 ER 1.7	2000. Expert statement on the oxidizing properties of 1-methylcyclopropene (1-MCP) active ingredient and 1-MCP formulation
APR-01-004 ER 6.7	2001. pH determination of an aqueous solution of 1-MCP formulation
00R-199 ER 2.4	2001. 1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): acute oral toxicity study in male and female rats

00R-200 ER 2.5	2001. 1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): acute dermal toxicity study in male and female rats
00R-180A ER 4.1	2001. 1-Methylcyclopropene: acute inhalation toxicity study in rats
00R-201 ER 2.6	2001. 1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): skin irritation study in rabbits
00R-202 ER 2.7	2001. 1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): eye irritation study in rabbits.
00R-203 ER 2.3	2001. 1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): Dermal sensitization study in guinea pigs - maximization test
00R-193A ER 2.8	2001. 1- Methylcyclopropene Vapor Released from 1-Methylcyclopropene Alpha Cyclodextrin Complex (3.3% a.i): S*almonella Typhimurium* Gene Mutagenicity Assay
00RC-194 ER 3.1	2001. 1- Methylcyclopropene Vapor Released from 1-Methylcyclopropene Alpha Cyclodextrin Complex (3.3% a.i): Chromosomal aberrations in Cultured Human Peripheral Blood Lymphocytes.
00RC-195 ER 3.3	2001. 1- Methylcyclopropene Vapor Released from 1-Methylcyclopropene Alpha Cyclodextrin Complex (3.3% a.i): CHO HGPRT Forward Mutation Assay with a Confirmatory assay and Duplicate Cultures
00R-232 ER 2.2	2001. 1-Methylcyclopropene: Micronucleus Assay in CD-1 Mouse Bone Marrow Cells
00R-183A ER 3.2	2001. 1-Methylcyclopropene: Two-week inhalation range-finding study in female rats
00R-183B ER 4.3	2001. 1-Methylcyclopropene: Two-week inhalation range-finding study in male rats
00R-183 ER 5.2	2001. 1-Methycyclopropene: Three-month inhalation toxicity study in rats

SAFETY DATA SHEET

Safety Data Sheet according to Directive 2001/58/EC

1. PRODUCT AND COMPANY IDENTIFICATION

Product name:

SmartFresh(TM) 3.3% Technology

Product Use Description: Plant growth regulator.

Supplier Rohm and Haas Company
Herald Way
Coventry CV3 2RQ United Kingdom
Telephone:+44 (0) 24-7665-4400

Emergency telephone number

United Kingdom +44 (0)191-4898181

2. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a preparation.

Component	CAS-No.	EINECS-No.	Concentration	Classification
Cyclodextrin A.I.	10016-20-3	233-007-4	80,0 - <95,0%	Xi R36

3. HAZARDS IDENTIFICATION

This product is not hazardous according to EEC Directives 67/548/EEC and 99/45/EC.

4. FIRST AID MEASURES

Inhalation: Move to fresh air.
Skin contact: Wash with water and soap as a precaution. If skin irritation persists, call a physician.
Eye contact: Rinse with plenty of water. If eye irritation persists, consult a specialist.
Ingestion: Drink 1 or 2 glasses of water. Consult a physician if necessary. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use the following extinguishing media when fighting fires involving this material:
carbon dioxide (CO2)
dry powder
foam
water spray

Specific hazards during fire fighting: Dusts at sufficient concentrations can form explosive mixtures with air.
Special protective equipment for fire-fighters: Wear self-contained breathing apparatus and protective suit.
Further information:DO NOT use a solid stream of water A solid stream of water directed at this material may create a potentially explosive airborne dust mixture.
Contain run-off.
Remain upwind.
Avoid breathing smoke.
Cool closed containers exposed to fire with water spray.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment.
If exposed to material during clean-up operations, see SECTION 4, First Aid Measures, for actions to follow.

Environmental precautions
CAUTION: Keep spills and cleaning runoff out of municipal sewers and open bodies of water.

Methods for cleaning up
Keep spectators away.
Avoid breathing dust.
Transfer spilled material to suitable containers for recovery or disposal.

7. HANDLING AND STORAGE

Handling
Avoid high concentrations of dust in air and accumulation of dust on equipment.An airborne dust of this material can create a dust explosion. When handling and processing this material local exhaust ventilation may be required to control dust and reduce exposure to vapors. To prevent dust explosions employ bonding and grounding for operations capable of generating static electricity. Protect all equipment from explosions by following applicable guidelines. For electrical equipment follow local codes and applicable electrical classification. Do not handle material near food, feed or drinking water.
Further information on storage conditions: Completely empty bag into application equipment. Dispose empty bag in a sanitary landfill or by incineration as allowed by state and local authorities. Avoid breathing smoke.

Storage
Storage conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid all ignition sources. Do not store this material near food, feed or drinking water.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)
Exposure limits are listed below, if they exist.

Exposure controls
Eye protection: Chemical resistant goggles must be worn Eye protection worn must be compatible with respiratory protection system employed.
Hand protection: Chemical-resistant gloves should be worn whenever this material is handled. The glove(s) listed below may provide protection against permeation. (Gloves of other chemically resistant materials may not provide adequate protection): - Polyvinyl chloride-coated glove or other chemical-resistant rubber- coated glove Gloves should be removed and replaced immediately if there is any indication of degradation or chemical breakthrough. Rinse and remove gloves immediately after use. Wash hands with soap and water.
Respiratory protection: No personal respiratory protective equipment normally required. Use certified respiratory protection equipment meeting EU requirements(89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.
Protective measures: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower
Engineering measures: Use only in area provided with appropriate exhaust ventilation.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	powder
Colour	white
pH	not applicable
Boiling point/range	not applicable
Melting point/range	>200 °C

Flash point	not applicable
Ignition temperature	ca.400 °C
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapour pressure	negligible
Relative vapour density	not applicable
Water solubility	0,5 g/l
Relative density	No data available
Viscosity, dynamic	not applicable
Evaporation rate	not applicable
Percent volatility	0 - 6 % water
VOC's	3,1 - 3,5 g/cm3

NOTE: The physical data presented above are typical values and should not be construed as a specification.

10. STABILITY AND REACTIVITY

Hazardous reactions	None known. Stable
Materials to avoid	There are no known materials which are incompatible with this product.
Hazardous decomposition products	There are no known hazardous decomposition products for this material.,
polymerization	Product will not undergo polymerization.

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	LD50rat > 5.000 mg/kg
Acute inhalation toxicity	LC50rat 4 h> 2,5 mg/l (No deaths or clinical signs of toxicity were observed at this concentration)
Acute dermal toxicity	LD50rat > 5.000 mg/kg
Skin irritation	Rabbit slight irritation (US Classification) Rabbit No skin irritation (EEC Classification)
Eye irritation	Rabbit Moderate eye irritation (US Classification) Rabbit No eye irritation (EEC Classification)
Sensitization	Maximisation Test (GPMT)guinea pigNot a sensitizer.

Teratogenicity
Developmental toxicity (rat): no evidence of any developmental effects.
Mutagenicity
Ames mutagenicity: Non-mutagenic
In vivo micronucleus assay (mouse bone marrow cells): Not mutagenic

12. ECOLOGICAL INFORMATION

There is no data available for this product.

13. DISPOSAL CONSIDERATIONS

Environmental precautions:CAUTION: Keep spills and cleaning runoff out of municipal sewers and open bodies of water.

Disposal
For disposal, incinerate this material at a facility that complies with local, state, and federal regulations.

European Waste Catalogue (94/3 EC)	The definitive assignment of this material to the appropriate EWC group and thus its proper EWC code will depend on the use that is made of this material. If the material as delivered must be disposed of, or you require assistance with assigning the proper EWC code, please contact your local Rohm and Haas office

14. TRANSPORT INFORMATION

Classification for ROAD and Rail transport (ADR/RID):

Not regulated (Not dangerous for transport)

Classification for SEA transport (IMO-IMDG):

Not regulated (Not dangerous for transport)

Classification for AIR transport (IATA/ICAO):

Not regulated (Not dangerous for transport)

15. REGULATORY INFORMATION

Label

Classification and labeling have been performed according to EU directives 67/548/EEC and 99/45/EC including amendments.

Hazard symbol and Indication of danger

This product is not hazardous according to EEC Directives 67/548/EEC and 99/45/EC.

EU. EINECS (EINECS) This substance is not in EINECS, and so does not comply.
US. Toxic Substances Control Act (TSCA) This product is subject to regulation under the US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and is therefore exempt from U.S. Toxic Substances Control Act (TSCA) Inventory listing requirements.

16. OTHER INFORMATION

Further information

The Material Safety Data Sheet (MSDS) augments the label and should not be used in place of regulatory approved product labels which are attached to or accompanying the product container. This MSDS provides important health, safety and environmental information for personnel that are manufacturing, distributing, transporting and storing the product, including emergency responders and other product handlers. The label provides information specifically for product users.

Full text of the R-phrases given in Section 2

R36 Irritating to eyes.

Emergency telephone number

European Region	**+33 (0) 140025045**
United States of America	+1-215-592-3000

Legend

ACGIH	American Conference of Governmental Industrial Hygienists
BAc	Butyl acetate
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
STEL	Short Term Exposure Limit (STEL):
TLV	Threshold Limit Value
TWA	Time Weighted Average (TWA):
Bar denotes a revision from prior MSDS.	

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Version:1.0
Revision date: 30.03.2004

71297-2 07/17/2002 1|15

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE:

X Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number	Date of Issuance:
71297-2	JUL 17 2002

Term of Issuance
Unconditional

Name of Pesticide Product
SmartFresh™ Technology

Name and Address of Registrant (include ZIP Code):

AgroFresh a Rohm and Hass Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) subject to the comments listed below:

1. Make the following label changes:

a. Add the phrase, "EPA Registration No. 71297-2" to your label before you release the product for shipment

b. Add the appropriate Establishment Number to your label before you release the product for shipment

2. Submit five copies of the final printed labeling before you release this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Unconditional registration does not eliminate the need for continual reassessment of a pesticide. If EPA determines, at any time, that additional data are required to maintain in effect, an existing registration, the Agency will require submission of such data under Section 3(c)(2)(B) of FIFRA.

Signature of the Approving Official

Frank K. Andrea

JUL 17 2002

2/15

Master Label

SmartFresh™ Technology

A unique postharvest tool for counteracting many of the undesirable effects of both internal and external sources of ethylene on harvested fruit.

ACTIVE INGREDIENT:
1-Methylcyclopropene.....3.3%

OTHER INGREDIENTS.....96.7%

TOTAL.....100.0%

A: SUBLABEL – COMMERCIAL LABEL FOR THE TREATMENT OF APPLES, MELONS,
TOMATOES, PEARS, AVOCADOES, MANGOES, PAPAYAS, KIWIFRUIT, PEACHES,
NECTARINES , PLUMS, APRICOTS AND PERSIMMONS

B: SUBLABEL – COMMERCIAL LABEL FOR THE TREATMENT OF APPLES

EPA Reg. No. 71297-

Produced by: AgroFresh Inc.
A subsidiary of Rohm and Haas Company
Philadelphia, PA
Tel: 215-592-3000

ACCEPTED
JUL 17 2002
Under the Federal Insecticides, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71297-2

3/15

SUBLABEL – COMMERCIAL LABEL FOR THE TREATMENT OF APPLES, MELONS, TOMATOES, PEARS, AVOCADOES, MANGOES, PAPAYAS, KIWIFRUIT, PEACHES, NECTARINES, PLUMS, APRICOTS, AND PERSIMMONS

AgroFresh Inc
A subsidiary of Rohm and Haas Company
Philadelphia, PA. 19106
Tel: (215) 592-3000

SmartFresh™ Technology

Active Ingredient: 1-Methylcyclopropene 3.3%
Other Ingredients:.....96.7%
Total:..... 100.0%

EPA REGISTRATION NO. 71297-
EPA EST. NO. 707-PA-003

NOTICE: Before using this product, read the entire Precautionary Statements, Conditions of Sale and Warranty, Directions for Use, Use Restrictions and Storage and Disposal Instructions. If the Conditions of Sale and Warranty are not acceptable, return the product in its generating system unopened and unused within thirty days of purchase to the place of purchase.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF IN EYES: Flush with plenty of water for at least 15 minutes. Call a physician if irritation persists.
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.
IF SWALLOWED: Dilute by drinking 1 or 2 glasses of water and call a physician.

Net Contents:

Generator:

System 18: 1.2 oz (34.0 grams)
System 25: 1.7 oz (46.9 grams)
System 34: 2.3 oz (64.7 grams)
System 46: 3.2oz (89.3 grams)
System 64: 4.3 oz (123.2 grams)
System 82: 5.5 oz (155.3 grams)
System 100: 6.6 oz (187.9 grams)
System 118: 7.8 oz (220.0 grams)
System 136: 8.6 oz (244.6 grams)
System 154: 9.8 oz (278.5 grams)
System 172: 10.9 oz (310.6 grams)

System 5: 0.17 oz (4.9 grams)
System 7: 0.24 oz (6.8 grams)
System 10: 0.33 oz (9.4 grams)
System 14: 0.45 oz (12.9 grams)
System 19: 0.63 oz (17.8 grams)
System 26: 0.87 oz (24.6 grams)

4/15

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes slight eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators of this product must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material

Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Workers Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covere by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas prior to venting the volatile active ingredient from the treatment room.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, prior to venting the volatile active ingredient from the treatment room is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Respirator

CONDITIONS OF SALE AND WARRANTY

AgroFresh, Inc warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. AgroFresh Inc **MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES EITHER OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.** Handling, storage and use of the product by Buyer or User are beyond the control of AgroFresh Inc. and Seller. Risks such as crop injury, ineffectiveness or other unintended consequences resulting from, but not limited to, weather or soil conditions, presence of other materials, disease, pests, drift to other crops or property, or failure to follo label directions will be assumed by the Buyer or User. **IN NO CASE WILL AgroFresh OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT.**

GENERAL INFORMATION

SmartFresh™ is a powder that, when mixed with water in a proprietary generating system, releases the volatile active ingredient 1-methylcyclopropene (1-MCP).

SmartFresh™ is a unique postharvest tool for counteracting many of the undesirable effects of both internal (produced within the fruit) and external sources of ethylene on harvested fruit. By counteracting ethylene, SmartFresh™ provides many benefits to the fruit during transport and storage including:

. Maintaining firmness
. Maintaining titratable acidity
. Preventing superficial scald and soft scald on pome fruit
. Reducing internal ethylene production
. Protection from external sources of ethylene
. Reducing fruit respiration
. Delaying ripening and senescence
. Reducing incidence of peel greasiness in apples
. Reducing incidence of core flush and mealiness in pome fruit
. Reducing chilling injury

SmartFresh™ can be used immediately after harvest, prior to storage, prior to shipment and/or just prior to sale. SmartFresh™ is effective under both cool (below 55 °F, 13 °C) and warm (above 55°F, 13°C) temperature conditions. To realize maximum benefit in controlling senescence, products should be treated as soon as possible after harvest.

Harvested fruits must be exposed to the volatile active ingredient of SmartFresh™ in enclosed areas, such as storage rooms, greenhouses, coolers, shipping containers, enclosed truck trailers, or ambient temperature, refrigerated, or controlled atmosphere food storage facilities. This product is not intended for use outdoors or in other non-enclosed areas. These enclosed treatment areas should be gas tight as leakage will reduce SmartFresh™'s effectiveness.

6/15

Directions For Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling . Do not appl this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation. All applicable directions, restrictions, precautions and conditions of sale and warranty are to be followed. This labeling must be in the user's possession during application.

Fruit Storage Conditions

SmartFresh™ is compatible with and complementary to fruit stored under both controlled atmosphere and regular air fruit storage conditions. SmartFresh™ must be used in air tight treatment areas.

Timing Of Harvest And Application

SmartFresh™ should be added to the treatment area containing fruit immediately after harvest, upon entering storage or in transit. To realize maximum benefit for optimum quality, fruit should be pre-cooled promptly and SmartFresh™ should be applied in the treatment area as soon after harvest as possible and before the climacteric peak of respiration has occurred. Best results from SmartFresh™ are obtained with fruit at the optimum maturity level for long term storage. After application, fruit not for immediate sale must be stored, according to good standard commercial practices, in either refrigerated air or controlled atmosphere. Storage in controlled atmosphere is recommended for fruit that is to be held longer than 6 months.

It must be emphasized that maintaining the cold chain (keeping the fruit cool at all times) and strict adherence to phytosanitary practices remain essential in maintaining safe and high-quality fruit. For optimum control of superficial scald on pome fruits, SmartFresh™ must be applied within two weeks of harvest.

APPLICATION METHOD

Prior to application, ensure that the treatment area can be properly and promptly sealed following application.

SmartFresh™ is applied by the use of a proprietary generator system. See Table 1 and Table 2 to select the appropriate generator system for the fruit and the size of the treatment area. Fill the treatment area with fruit. Place the appropriate generator on a stable surface of the treatment area in a position that would be within the flow of air from the internal refrigeration system.

Remove the lid from the generator and the protective tape which covers the start button. Push the start button (which will illuminate red) to start the generator. With the generator running, add 2 gallons (8 liters) of water at a temperature between 20 degrees and 40 degrees Centigrade (68 to 104 degrees Fahrenheit) to the generator. Immediately leave the storage area and seal the door in order to contain the 1-MCP vapor and ensure the maximum efficacy of 1-MCP. The release of the 1-MCP to the area will start several minutes after the water is added to the generator.

After the area is sealed, post a sign on all of the entrances to the treatment area. The sign should read **"CAUTION. Do not enter area. SmartFresh™ treatment in progress."** The doors to the storage area should remain sealed for 24 hours to ensure effective SmartFresh™ treatment. Entrance to the room prior to 24 hours will invalidate the treatment. During the treatment, the internal refrigerated air circulation should be running to ensure good air circulation within the room. All vents to outside air should be closed, and any ethylene scrubbing devices or ozone generating equipment should be turned off. At the end of the SmartFresh™ treatment period, vent the treated room by opening the doors for a minimum of thirty minutes with continued full internal ventilation before allowing workers to enter. At the end of the

7/15

room venting, remove the generator. The spent water contained in the generator can be disposed by pouring down a suitable drain. Treated fruit not intended for immediate sale should be stored according to good, standard commercial practices, in either refrigerated air or controlled atmosphere. Storage in controlled atmosphere conditions is recommended for fruit that is planned to be held longer than 6 months.

Restrictions

Restricted Entry Period (REI): 30 minutes after room has been vented

Maximum season use rate: One application at a maximum use rate of 1 ppm (volume/volume in air) as delivered by appropriate sized generator (see Table 1 and Table 2 for generator selection)

Do not smoke during the SmartFresh™ application.

For temperate treefruit (apples, pears, plums, apricots, peaches, nectarines and kiwifruit), apply SmartFresh™ within two weeks of harvest.

For tropical treefruits (avocadoes, mangoes, papayas, persimmons), tomatoes and melons, apply within three days of harvest

Do not treat fruit stressed from poor fertility, heat, drought or sunscald

Do not treat fruit that have had a pre-harvest application of ethephon

8/15

TABLE 1. Selection Of Generator For Treatment Of Apples, Melons, Tomatoes

Selection based on volume of treatment area. Calculate the treatment area volume by measuring the length, width and height of the treatment area in feet. Multiply these three numbers together to obtain the treatment area volume in cubic feet. For example, if a room is 4 feet wide , 5 feet long and 5 feet high, the treatment area volume equals 100 cubic feet.

Treatment Area Size (empty volume)	Generator Type	Total SmartFresh™ In Generator	
ft^3		Oz.	Grams
18,000 – 25,000	System 18	1.2	34.0
25,000 – 34,000	System 25	1.7	46.9
34,000 – 46,000	System 34	2.3	64.7
46,000 – 64,000	System 46	3.2	89.3
64,000 – 82,000	System 64	4.3	123.2
82,000 – 100,000	System 82	5.5	155.3
100,000 – 118,000	System 100	6.6	187.9
118,000 – 136,000	System 118	7.8	220.0
136,000 – 154,000	System 136	8.6	244.6
154,000 – 172,000	System 154	9.8	278.5
172,000 – 190,000	System 172	11.0	310.6

Note: Use multiple generators for treatment area sizes greater than those listed in the above table.

Table 2: Selection Of Generator For Treatment Of Pears, Avocadoes, Mangoes, Papayas, Kiwifruit, Peaches, Nectarines, Plums, Apricots and Persimmons

Selection based on volume of treatment area. Calculate the treatment area volume by measuring the length, width and height of the treatment area in feet. Multiply these three numbers together to obtain the treatment area volume in cubic feet. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the treatment area volume equals 100 cubic feet.

Treatment Area Size (empty volume)	Generator Type	Total SmartFresh™ in Generator	
Ft^3		Oz.	Grams
5,000 – 7,000	System 5	0.17	4.9
7,000 – 10,000	System 7	0.24	6.8
10,000 – 14,000	System 10	0.33	9.4
14,000 – 19,000	System 14	0.45	12.9
19,000 – 26,000	System 19	0.63	17.8
26,000 – 36,000	System 26	0.87	24.6

Note: Use multiple generators for treatment area sizes greater than those listed in the above table.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Container Disposal: Triple rinse the generator with water after use. Instructions for returning the used generators will be provided by AgroFresh Inc.

SmartFresh™ is a registered trademark of AgroFresh Inc./Rohm and Haas Company

AgroFresh Inc.
A Fully-Owned Subsidiary of Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA. 19106
(215) 592-3000

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10/15

SUBLABEL – COMMERCIAL LABEL FOR THE TREATMENT OF APPLES

AgroFresh Inc
A subsidiary of Rohm and Haas Company
Philadelphia, PA. 19106
Tel: (215) 592-3000

SmartFresh™ Technology

Active Ingredient: 1-Methylcyclopropene 3.3%
Other Ingredients: 96.7%
Total: 100.0%

EPA REGISTRATION NO. 71297-
EPA EST. NO. 707-PA-003

NOTICE: Before using this product, read the entire Precautionary Statements, Conditions of Sale and Warranty, Directions for Use, Use Restrictions and Storage and Disposal Instructions. If the Conditions of Sale and Warranty are not acceptable, return the product in its generating system unopened and unused within thirty days of purchase to the place of purchase.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF IN EYES: Flush with plenty of water for at least 15 minutes. Call a physician if irritation persists.
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.
IF SWALLOWED: Dilute by drinking 1 or 2 glasses of water and call a physician.

Net Contents:

Generator:

System 18:	1.2 oz (34.0 grams)
System 25:	1.7 oz (46.9 grams)
System 34:	2.3 oz (64.7 grams)
System 46:	3.2oz (89.3 grams)
System 64:	4.3 oz (123.2 grams)
System 82:	5.5 oz (155.3 grams)
System 100:	6.6 oz (187.9 grams)
System 118:	7.8 oz (220.0 grams)
System 136:	8.6 oz (244.6 grams)
System 154:	9.8 oz (278.5 grams)
System 172:	10.9 oz (310.6 grams)

11/15

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes slight eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators of this product must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material

Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Workers Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas prior to venting the volatile active ingredient from the treatment room.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, prior to venting the volatile active ingredient from the treatment room is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Respirator

12/15

CONDITIONS OF SALE AND WARRANTY

AgroFresh, Inc warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. AgroFresh Inc **MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES EITHER OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.** Handling, storage and use of the product by Buyer or User are beyond the control of AgroFresh Inc. and Seller. Risks such as crop injury, ineffectiveness or other unintended consequences resulting from, but not limited to, weather or soil conditions, presence of other materials, disease, pests, drift to other crops or property, or failure to follo label directions will be assumed by the Buyer or User. **IN NO CASE WILL AgroFresh OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT.**

GENERAL INFORMATION

SmartFresh™ is a powder that, when mixed with water in a proprietary generating system, releases the volatile active ingredient 1-methylcyclopropene (1-MCP).

SmartFresh™ is a unique postharvest tool for counteracting many of the undesirable effects of both internal (produced within the fruit) and external sources of ethylene on harvested fruit. By counteracting ethylene, SmartFresh™ provides many benefits to the fruit during transport and storage including:

. Maintaining firmness
. Maintaining titratable acidity
. Preventing superficial scald and soft scald on pome fruit
. Reducing internal ethylene production
. Protection from external sources of ethylene
. Reducing fruit respiration
. Delaying ripening and senescence
. Reducing incidence of peel greasiness in apples
. Reducing incidence of core flush and mealiness in pome fruit
. Reducing chilling injury

SmartFresh™ can be used immediately after harvest, prior to storage, prior to shipment and/or just prior to sale. SmartFresh™ is effective under both cool (below 55 °F, 13 °C) and warm (above 55°F, 13°C) temperature conditions. To realize maximum benefit in controlling senescence, products should be treated as soon as possible after harvest.

Harvested fruits must be exposed to the volatile active ingredient of SmartFresh™ in enclosed areas, such as storage rooms, greenhouses, coolers, shipping containers, enclosed truck trailers, or ambient temperature, refrigerated, or controlled atmosphere food storage facilities. This product is not intended for use outdoors or in other non-enclosed areas. These enclosed treatment areas should be gas tight as leakage will reduce SmartFresh™'s effectiveness.

Directions For Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling . Do not appl this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation. All applicable directions, restrictions, precautions and conditions of sale and warranty are to be followed. This labeling must be in the user's possession during application.

Fruit Storage Conditions

SmartFresh™ is compatible with and complementary to fruit stored under both controlled atmosphere and regular air fruit storage conditions. SmartFresh™ must be used in air tight treatment areas.

Timing Of Harvest And Application

SmartFresh™ should be added to the treatment area containing fruit immediately after harvest, upon entering storage or in transit. To realize maximum benefit for optimum quality, fruit should be pre-cooled promptly and SmartFresh™ should be applied in the treatment area as soon after harvest as possible and before the climacteric peak of respiration has occurred. Best results from SmartFresh™ are obtained with fruit at the optimum maturity level for long term storage. After application, fruit not for immediate sale must be stored, according to good standard commercial practices, in either refrigerated air or controlled atmosphere. Storage in controlled atmosphere is recommended for fruit that is to be held longer than 6 months.

It must be emphasized that maintaining the cold chain (keeping the fruit cool at all times) and strict adherence to phytosanitary practices remain essential in maintaining safe and high-quality fruit. For optimum control of superficial scald on pome fruits, SmartFresh™ must be applied within two weeks of harvest.

APPLICATION METHOD

Prior to application, ensure that the treatment area can be properly and promptly sealed following application.

SmartFresh™ is applied by the use of a proprietary generator system. See Table 1 to select the appropriate generator system for the fruit and the size of the treatment area. Fill the treatment area with fruit. Place the appropriate generator on a stable surface of the treatment area in a position that would be within the flow of air from the internal refrigeration system.

Remove the lid from the generator and the protective tape which covers the start button. Push the start button (which will illuminate red) to start the generator. With the generator running, add 2 gallons (8 liters) of water at a temperature between 20 degrees and 40 degrees Centigrade (68 to 104 degrees Fahrenheit) to the generator. Immediately leave the storage area and seal the door in order to contain the 1-MCP vapor and ensure the maximum efficacy of 1-MCP. The release of the 1-MCP to the area will start several minutes after the water is added to the generator.

After the area is sealed, post a sign on all of the entrances to the treatment area. The sign should read **"CAUTION. Do not enter area. SmartFresh™ treatment in progress."** The doors to the storage area should remain sealed for 24 hours to ensure effective SmartFresh™ treatment. Entrance to the room prior to 24 hours will invalidate the treatment. During the treatment, the internal refrigerated air circulation should be running to ensure good air circulation within the room. All vents to outside air should be closed, and any ethylene scrubbing devices or ozone generating equipment should be turned off. At the end of the SmartFresh™ treatment period, vent the treated room by opening the doors for a minimum of thirty minutes with continued full internal ventilation before allowing workers to enter. At the end of the

room venting, remove the generator. The spent water contained in the generator can be disposed by pouring down a suitable drain. Treated fruit not intended for immediate sale should be stored according to good, standard commercial practices, in either refrigerated air or controlled atmosphere. Storage in controlled atmosphere conditions is recommended for fruit that is planned to be held longer than 6 months.

Restrictions

Restricted Entry Period (REI): 30 minutes after room has been vented

Maximum season use rate: One application at a maximum use rate of 1 ppm (volume/volume in air) as delivered by appropriate sized generator (see Table 1 for generator selection)

Do not smoke during the SmartFresh™ application.

Apply SmartFresh™ within two weeks of harvest

Do not treat fruit stressed from poor fertility, heat, drought or sunscald

Do not treat fruit that have had a pre-harvest application of ethephon

TABLE 1. Selection Of Generator For Treatment Of Apples

Selection based on volume of treatment area. Calculate the treatment area volume by measuring the length, width and height of the treatment area in feet. Multiply these three numbers together to obtain the treatment area volume in cubic feet. For example, if a room is 4 feet wide , 5 feet long and 5 feet high, the treatment area volume equals 100 cubic feet.

Treatment Area Size (empty volume)	Generator Type	Total SmartFresh™ In Generator	
ft^3		Oz.	Grams
18,000 – 25,000	System 18	1.2	34.0
25,000 – 34,000	System 25	1.7	46.9
34,000 – 46,000	System 34	2.3	64.7
46,000 – 64,000	System 46	3.2	89.3
64,000 – 82,000	System 64	4.3	123.2
82,000 – 100,000	System 82	5.5	155.3
100,000 – 118,000	System 100	6.6	187.9
118,000 – 136,000	System 118	7.8	220.0
136,000 – 154,000	System 136	8.6	244.6
154,000 – 172,000	System 154	9.8	278.5
172,000 – 190,000	System 172	11.0	310.6

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Container Disposal: Triple rinse the generator with water after use. Instructions for returning the used generators will be provided by AgroFresh Inc.

SmartFresh™ is a registered trademark of AgroFresh Inc./Rohm and Haas Company

AgroFresh Inc.
A Fully-Owned Subsidiary of Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA. 19106
(215) 592-3000

RHL
07/01/02

STATE OF CALIFORNIA
DEPARTMENT OF PESTICIDE REGULATION
PESTICIDE REGISTRATION BRANCH
1001 I Street P.O. Box 4015
SACRAMENTO,CA 95812-4015

LICENSE No. 37501

CERTIFICATE OF REGISTRATION
FOR PESTICIDES

NON TRANSFERABLE

FIRM NAME

AGRO FRESH, INC., A WHOLLY OWNED SUBSIDIARY OF
ROHM AND HAAS COMPANY
100 INDEPENDENCE MALL WEST
PHILADELPHIA PA 19106-2399

FIRM NO: 71297

DATE OF ISSUE (MO DAY YEAR): 01/01/07

EXPIRES: DEC 31 2007

is authorized to manufacture, deliver or sell in California the products listed below. Registration is not an endorsement of approval by the Department of Pesticide Regulation of any product or any claim made for it. No reference may be made to the California Department of Pesticide Regulation in labeling or advertisements. Registration may be cancelled after hearing at any time for just cause. The composition of each product and the label on it must be the same as those submitted by the registrant. Only labels accepted by the Director may represent a pesticide.

REGISTRATION NUMBER	BRAND NAME
FULL REGISTRATIONS	
71297- 1-AA	ETHYLBLOC TECHNOLOGY
71297- 5-ML	MASTER LABEL - ETHYLBLOC SACHET
71297- 2-ZA	SMARTFRESH
71297- 50001-AA	SMARTFRESH ACTIVATOR KIT
71297- 3-AA	SMARTFRESH SMARTTABS

TOTAL PRODUCTS REGISTERED: 5

A CERTIFICATE OF REGISTRATION FOR PESTICIDES IS NOT TRANSFERABLE.
IF THERE IS A CHANGE IN BUSINESS OWNERSHIP, A NEW APPLICATION AND FEE(S) ARE NECESSARY.

Washington State Department of Agriculture
Pesticide Management Division
1111 Washington Street SE, 2nd Floor
PO Box 42591 Olympia WA 98504-2591
Telephone (360) 902-2030 Fax (360) 902-2093
E-Mail: pestreg@agr.wa.gov

Date Printed: 02/13/2007
SL

PESTICIDE REGISTRATION CERTIFICATE

01/01/2007 - 12/31/2008

71297 **AgroFresh Inc**
[Third Party: Kelly Registration Systems]

Mailing: 10115 Highway 142 N
Covington, GA 30014

Phone: (770) 788-4519
Fax: (770) 385-0342
E-Mail: stephanie@kellyreg.com
Web:

Contact: Stephanie Hacker
Consultant
10115 Highway 142 N
Covington, GA 30014

Phone: (770) 788-4519
Fax: (770) 385-0342
E-Mail: stephanie@kellyreg.com

The following pesticide products have been registered for distribution in the state of Washington through 12/31/2008 unless otherwise noted. This registration certificate supercedes any previous registration certificate.

N/R	EPA/State Reg. No.	Product Name	Label ID	Dept Use Only H&G ONLY	State RUP	File #
		SECTION 3				
	71297-2	SmartFresh Singles	NONE			2
	Approved: 01/01/2007	**Ingredients** Methylcyclopropene (3.3%)				
	71297-2	SmartFresh Technology	NONE			1
	Approved: 01/01/2007	**Ingredients** Methylcyclopropene (3.3%)				
	71297-3	SmartFresh SmartTabs	12-8-03			3
	Approved: 01/01/2007	**Ingredients** Methylcyclopropene (0.63%)				