Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Note REG2004-07

1-methylcyclopropene

The active ingredient 1-methylcyclopropene and its associated end-use product (EP), SmartFresh™ Technology containing 3.3% 1-methylcyclopropene, have been registered under Section 17 of the Pest Control Products Regulations for postharvest use on apples to delay fruit maturation and maintain fruit firmness.

This Regulatory Note provides a summary of data reviewed and the rationale for the proposed regulatory decision regarding these products.

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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1 800 267-6315 or (613) 736-3799
Facsimile: (613) 736-3798

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Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) has issued temporary registration for 1-methylcyclopropene and the associated end-use product, SmartFresh™ Technology, for postharvest use on apples to delay fruit maturation and maintain fruit firmness. As a condition of this temporary, AgroFresh Inc. will be carrying out additional value studies to support the maximum application rate of 1.0 ppm and to confirm efficacy in commercial-scale apple storage facilities. Following the review of this information, the PMRA will publish a proposed regulatory decision document and request comments from interested parties before proceeding with a final regulatory decision.

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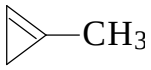
1.0 The active substance, its properties and uses

1.1 Identity

Technical grade active ingredient (TGAI) identification

Active substance		1-methylcyclopropene (1-MCP)
Function		plant growth regulator
Chemical name		
1.	International Union of Pure and Applied Chemistry	1-methylcyclopropene
2.	Chemical Abstracts Service (CAS)	1-methylcyclopropene
CAS number		438388
Molecular formula		C_4H_6
Molecular weight		54.09
Structural formula		
Nominal purity of active		96.0%, nominal (limits: 93.0–99.0%)
Identity of relevant impurities of toxicological, environmental or other significance		The technical grade 1-MCP does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. One of the impurities, 3-chloro-2-methylpropene (CMP) (unreacted starting material), which is listed on the Statement of Product Specification Form at 0.017% nominal, has been listed by the National Toxicology Program as reasonably anticipated to be a cancer causing agent.

1.2 Physical and chemical properties

Table 1.2.1 Technical product: 1-MCP

Property	Result	Comment
Colour and physical state	Colourless gas	
Odour	Sharp, light sweetish smell	
Melting point or range	Not applicable	The technical product is a gas under ambient conditions.
Boiling point or range	Not applicable	The technical product is a gas under ambient conditions.
Density	2.24 g/L (calculated) at 20°C	Based on the ideal gas law.
Vapour pressure at 20°C	2×10^5 Pa at 25°C (calculated)	Very high volatility.
Henry's law constant at 20°C	4.38×10^9 Pa	Potential to volatilize from moist surfaces and water.
Ultraviolet (UV)–visible spectrum	No absorbance maxima observed above 205 nm.	Negligible potential for phototransformation.
Solubility in water at 20°C	137 mg/L at 20°C; no pH effect	Very soluble; however, based on methodology and nature of compound, the result is difficult to interpret.
Solubility (g/L) in organic solvents at 20°C	Solvent — Solubility (g/L) acetone — 2.4 dichloromethane — 2.0 ethyl acetate — 12.5 heptane — 2.5 methanol — 11.25 xylene — 2.3	In general, solubility appears to increase with increasing organic solvent polarity.
n-octanol–water partition coefficient (K_{ow})	log K_{ow} = 2.4 (no pH effect)	Negligible potential based on chemical structure.
Dissociation constant (pK_a)	Not applicable.	The product contains no acid or base functionality.

Property	Result	Comment
Stability (temperature, metal)	Chemically unstable and begins to self-react immediately.	Technical product is never isolated.

Table 1.2.2 EP: SmartFresh™ Technology

Property	Result
Colour	White
Odour	No characteristic odour
Physical state	Powder (solid)
Formulation type	Water soluble powder; dust
Guarantee	1-methylcyclopropene, 3.3% (limits: 3.135–3.465%)
Formulants	The product does not contain any USEPA List 1 formulants or formulants known to be TSMP Track 1 substances.
Container material and description	Water soluble polyvinyl alcohol (PVA) film pouch inside a moulded polyethylene cylindrical vessel.
Bulk density	Pour density = 0.27 g/mL at 20°C Tap density = 0.38 g/mL at 20°C
pH of 1% dispersion in water	5.7 at 24°C
Oxidizing or reducing action	This product does not contain any strong oxidising or reducing agents.
Storage stability	Based on the results of a 1 year storage stability study (under ambient conditions), the active ingredient (a.i.) is stable (relative a.i. loss was 2% and sample weight change was insignificant). Also, the integrity of the PVA package was not compromised.
Explodability	This product is not potentially explosive.

1.3 Details of uses and further information

1-methylcyclopropene (1-MCP) is an ethylene inhibiting plant growth regulator. SmartFresh™ Technology, formulated as a soluble powder containing 3.3% 1-MCP, is proposed for postharvest use in pome fruit to maintain fruit firmness by delaying ripening. Application is made by means of a proprietary generator device within which is placed one water soluble packet containing the product. This device is placed in such a

manner that it is within the airflow of the internal refrigeration system of the enclosed room in which it is applied. The active ingredient is released as a vapour following addition of the soluble packet to the water in the device, and is circulated throughout the room for a 24-hour period. There are 11 soluble packet sizes that range from 34.0 to 310.6 g product for treatment of room volumes that range from 500 to 5400 m^3. The specific concentration of 1-MCP achieved is a function of the size of the soluble packet and the specific volume of the treatment room, so that 1-MCP can be delivered at concentrations ranging from approximately 0.725 to 1.0 ppm. SmartFresh™ Technology is proposed for application in enclosed areas that include storage rooms, greenhouses, coolers, shipping containers, enclosed truck trailers, or ambient temperature, refrigerated or controlled atmosphere food storage facilities. Following treatment that is proposed to take place within two weeks of harvest, fruit not destined for immediate marketing are then stored in accordance with standard commercial practices.

The submitted data support the use of SmartFresh™ Technology on apples only. The product is supportable for application for a 24-hour period in gas-tight, ambient temperature, refrigerated or controlled atmosphere food storage facilities. The data submitted support application that is initiated within 3 days after harvest to apples that were cooled to 0–3°C within one day after harvest, or support application that is initiated within one day after harvest at temperatures of up to 23°C. Treated fruit may be marketed immediately or stored in either refrigerated air or controlled atmosphere facilities.

Efficacy data were sufficient to support the principal claim of maintaining fruit firmness for SmartFresh™ applied at the proposed maximum rate of 1.0 ppm 1-MCP. The following additional claims were supported: delay in rise of internal ethylene production and respiration, delay in ripening and senescence, and reducing superficial scald. Data were either absent or insufficient to support the following claims: maintaining titratable acidity, preventing soft scald, protection from external sources of ethylene, reducing incidence of peel greasiness in apples, reducing incidence of core flush, reducing incidence of mealiness and reducing chilling injury.

Additional data are required to support the unconditional registration of the proposed 1-MCP rate of 1.0 ppm and to confirm efficacy in commercial scale apple storage facilities of up to 5400 m^3 with the proposed application equipment.

2.0 Methods of analysis

2.1 Analytical methods for analysis of the active substance as manufactured

The active ingredient and major impurities in the technical product were determined by gas chromatography using a flame ionisation detector (GC-FID). Since 1-MCP is a very reactive, unstable gas, the GC was calibrated with the isobutylene standard since it is stable and readily available. Isobutylene is expected to have a similar GC-FID response compared to 1-MCP. The method was assessed to have acceptable accuracy, precision and linearity to a suitable limit of quantitation (<0.1%). Representative chromatograms of

the standard and the samples show no interfering peaks and indicate that the method is sufficiently specific for the determination. The identities of the active ingredient and impurities were confirmed by spectral methods.

2.2 Analytical methods for formulation analysis

The active ingredient in SmartFresh™ Technology was determined by GC-FID. The method is identical to the method used for the technical product and was assessed to be specific, precise and accurate for use as an enforcement analytical method. Representative chromatograms of the samples and the formulation blank show no interferences around the retention vicinity of the active.

2.3 Methods for residue analysis

2.3.1 Methods for environmental residue analysis

Waiver requests were submitted in place of analytical methods for the determination of 1-MCP in environmental matrices (soil, sediment, water as well as plant and animal biota). The waiver requests were based on the negligible potential for 1-MCP to accumulate because of instantaneous dilution of the gaseous compound with environmental air and because degradation of 1-MCP in the atmosphere is rapid. The waiver requests are acceptable and, therefore, postregistration methods are not considered necessary for 1-MCP.

2.3.2 Multiresidue methods for residue analysis

The active ingredient, 1-MCP, could not be subjected to a recognized and published multiresidue analytical method due to its volatility and reactivity.

2.3.3 Methods for residue analysis of plants and plant products

The GC/FID method (Report No. AF-01-173) was proposed as the enforcement method for the determination of residues of 1-MCP in apples. Briefly, samples were extracted by blending with a basic (pH 11) saturated ammonium sulphate solution in a custom-made Teflon cutting assembly attached to a standard blender jar to form an airtight unit. A valve was sealed to the top of the cutting assembly to allow head space samples to be collected from the unit or spiking to be made. Residues of 1-MCP were released as a gas and trapped in the head space of the assembly. The head space was then sampled directly for analysis by GC/FID. Isobutene was used as an external calibration standard due to its stability and structural similarity to 1-MCP. The LOQ for the GC/FID method was reported to be 0.01 mg/kg. Method validation demonstrated acceptable mean recoveries (87–95%) and standard deviations (less than 20%) at spiking levels of 0.01 and 0.1 mg/kg. The independent laboratory validation (ILV) of the GC/FID method was successful, resulting in acceptable recoveries of 76–96%, obtained when apples were spiked with 1-MCP at 0.01 mg/kg and 0.1 mg/kg.

2.3.4 Methods for residue analysis of food of animal origin

Since no measurable residues of 1-MCP are expected to transfer to livestock matrices following exposure to treated feed (apple pomace), an analytical method for the detection of 1-MCP residues in meat and milk was not required.

3.0 Impact on human and animal health

3.1 Integrated toxicological summary

A detailed review of the toxicological database available for the TGAI, 1-MCP, and the EP, SmartFresh™ Technology, has been completed. Data submitted for the registration of the new TGAI and EP included numerous waivers and a limited number of studies based on Use-site Category 5. The scientific and regulatory quality of the toxicology database is considered sufficient to adequately define the toxicity of this chemical for its intended purpose.

Absorption of 1-MCP was rapid and limited following administration via 4-hour whole body inhalation (100 ppm and 1000 ppm). Less than 1.8% of the administered substance was found in the tissues of the sacrificed animals (20 hours after exposure) and less than 5% was excreted, mainly via urine, over the 24 hour test period. The highest concentrations of the test substance seen in whole blood or in plasma were noted at the end of exposure (4 hours), after which the levels dropped rapidly. The study indicates that rats do not appear to extensively absorb or metabolize 1-MCP. Limited levels of ^{14}C-1-methylcyclopropene were used and recovered, thereby making it impossible to determine a metabolic pathway due to the inability to identify or quantify the metabolites. It is most likely that the test substance is primarily inhaled and exhaled.

1-MCP was not tested for toxicity by the oral and dermal routes (waivers were submitted and granted) due to the nature of the substance (gas at room temperature). This was also the case for the eye and skin irritation test. 1-MCP was of low toxicity via the inhalation route. The SmartFresh™ formulation is of low toxicity by the oral and dermal route, minimally irritating to eyes and skin and is a non-sensitizer (see Appendix I). An inhalation study was not conducted as the study could not be done on the formulated product.

Short-term oral studies were not conducted (waivers submitted and granted) due to the nature of the test substance (a gas at room temperature) and the negligible potential daily intakes (PDIs). Two range-finding rat inhalation studies (one male and one female) and a 90-day rat inhalation study was performed via 6-hour nose only repeat dose.

Hematological findings were generally characterized by decreased red blood cells (RBCs), hematocrit (HCT) and hemoglobin (HGB) in both sexes at the higher doses for the range-finding and 90-day inhalation studies. Organ weight findings included an increase in the absolute and relative spleen weight in both sexes as the higher dose in the

range-finding and 90-day inhalation study. Histopathology findings indicated an increase in hyaline droplets in the males at mid dose levels in both the male range-finding and the males of the 90-day inhalation study. Gross pathology observations included an enlargement of the spleen and extramedullary hematopoiesis in both the female range-finding and 90-day inhalation studies at the high dose. Findings specific to the 90-day inhalation study included an increase in absolute and relative liver weight in both sexes and an increase in kidney weight in females at the higher dose. The lowest observed adverse effect level (LOAEL) was set, based on the increase in hyaline droplets in the kidney, at 107 mg/kg bw/day and the no observed adverse effect level (NOAEL) was set at 9 mg/kg bw/day.

1-MCP was tested in a battery of in vitro (bacterial and mammalian cell gene mutation assay and mammalian cells chromosomal aberration assays) and in vivo (rat micronucleus assay) mutagenicity studies. There was no evidence of genotoxicity potential in any of these assays; therefore, the weight of the evidence suggests that 1-MCP was not genotoxic under the conditions of the tests performed.

A rat developmental toxicity study indicates that 1-MCP was not teratogenic. Maternal findings included darkened and enlarged spleens at the mid dose and a decrease in body weight gain during the first few days of treatment at the high dose. Based on the spleen findings the maternal LOAEL was set at 142 mg/kg bw/day and the NOAEL was set at 45 mg/kg bw/day. There were no adverse fetal findings throughout the study, thereby leaving the LOAEL undetermined and the NOAEL set at 440 mg/kg bw/day.

No long term studies, reproductive studies or rabbit developmental studies were performed with 1-MCP (waivers were submitted and granted). The genotoxicity studies were negative, no significant adverse effects or adverse endocrine effects were observed in the 90-day rat inhalation study and the metabolism study indicated that the compound does not appear to be extensively metabolized or absorbed by the body following exposure.

The data available is mainly from the 90-day rat inhalation study, two range-finding rat inhalation studies, a rat developmental toxicity study and a metabolism study. Findings from the 90-day inhalation study regarding the kidney include hyaline droplets that were observed in male rats only. This finding was confirmed in the male 2-week range-finding study. This finding is consistent with α_{2u}-globulin type degeneration, which produces a very high concentration of serum protein globulin thought to be by epithelial cells of the kidney tubule when exposed to high doses of a variety of exogenous chemicals. This type of degeneration is especially evident in male rats. No additional studies were conducted to determine with certainty that this is the cause of the hyaline droplets and, on the basis of this, the hyaline droplets are considered adverse. In addition, the absolute kidney weight was increased in females in the 90-day inhalation study.

Numerous spleen effects were observed in the rat inhalation studies. Darkened and discoloured spleens were seen in females in the range-finding inhalation study and in the

developmental toxicity study. Absolute and relative spleen weights were increased in all the inhalation studies. In the developmental toxicity study the spleen was enlarged, however the organ was not weighed. In the female range-finding and 90-day rat inhalation study, extramedullary hematopoesis was observed. Hemosiderin, primarily in the red pulp, was also noted in the 90-day study. In the range-finding inhalations studies and 90-day inhalation study, RBCs, HCT and HGB were decreased. The observed effects on the spleen and the decrease in RBCs, HGB and HCT may be indicative of an anaemia but data are insufficient to confirm this.

An increase in relative liver weight was noted in both sexes in the 90-day rat inhalation study and an increase in absolute liver weight was observed in females in the same study. Similarly, changes in body weight (decreased) and liver weights (increased relative and absolute) were confined to the high dose in the 90-day inhalation study.

3.2 Determination of acceptable daily intake (ADI)

No chronic/oncogenicity studies or subchronic oral or dermal studies were performed. A 90-day rat inhalation and a rat teratogenicity study were performed. In the absence of additional data, a definitive ADI could not be determined. However, based on an absence of adverse effects in the studies performed, it is considered appropriate to conduct a risk assessment based on a margin of exposure (MOE) approach. The toxicological endpoint considered most appropriate for risk assessment is the increase in hyaline droplets observed in male rats in the 90-day inhalation study. The lowest NOAEL for hyaline droplets was 9.0 mg/kg bw/day. PMRA calculates the PDI to be 0.000011 mg/kg bw/day. The MOE is, therefore, calculated to be 800 000, which is considered to be more than adequate.

$$\text{MOE} = \frac{\text{NOAEL}}{\text{PDI}} = \frac{9.0 \text{ mg/kg bw/day}}{0.000011 \text{ mg/kg bw/day}}$$

MOE = 800 000

3.3 Acute reference dose (ARfD)

An acute reference dose (ARfD) was not established since 1-MCP was considered unlikely to present an acute hazard.

3.4 Toxicological endpoint selection—occupational and bystander risk assessment

It is recommended that the rat 90-day inhalation study with a NOAEL of 9.0 mg/kg bw/day be used for short- to intermediate-term exposure scenarios. A MOE of 1000 is recommended based on 100× to account for intra- and inter-species differences as well as an additional 10× to account for a reduced data package.

Dermal absorption

Since exposure by the dermal route is considered to be minimal, dermal absorption data is not required for the risk assessment.

3.5 Impact on human health arising from exposure to the active substance or to impurities contained in it

AgroFresh Inc. has applied to register a new active ingredient, 1-MCP, and a new EP, SmartFresh™ Technology. SmartFresh™ Technology is a postharvest tool intended to counteract many of the undesirable effects of internal (produced within the fruit) ethylene production in harvested apples. Harvested apples must be exposed to the volatile active ingredient of SmartFresh™ Technology in gas-tight, enclosed areas that include ambient temperature, refrigerated or controlled atmospheric food storage facilities. This product is not intended for use outdoors or in non-enclosed areas. SmartFresh™ Technology may be applied within three days after harvest for fruit immediately cooled to 0 to 3°C within one day after harvest, or SmartFresh™ may be applied at temperatures of up to 23°C within one day after harvest. Only one application of SmartFresh™ Technology is permitted per crop of apples.

SmartFresh™ is formulated as a powder containing 3.3% 1-MCP, to be applied only with a SmartFresh™ generator. There are a number of SmartFresh™ Technology systems available. Based on the size of the treatment area, the appropriate SmartFresh™ Technology system is selected and used with the proper amount of 1-MCP required to produce the target application rate of 1 ppm. The appropriate amount of 1-MCP is prepackaged in an individual water soluble package. SmartFresh™ Technology is applied to the application area by placing the appropriate generator on a stable surface in the treatment area in a position that would be within the flow of air from the internal refrigeration system, pushing the start button (which will illuminate red) to start the generator, adding 8 L of water at a temperature between 20°C and 40°C to the generator, adding the water soluble pouch containing the appropriate amount of SmartFresh™ product to the generator, immediately leaving the storage area and sealing the door in order to contain the 1-MCP vapour and ensure maximum efficacy of 1-MCP. The release of 1-MCP to the area will start several minutes after the SmartFresh™ pouch is added to the generator. The doors to the storage area must remain sealed for 24 hours with all vents to outside air closed to ensure effective SmartFresh™ Technology treatment.

AgroFresh Inc. will hire and train a group of applicators to apply the product in Canada. The application service is triggered by a received order from a customer specifying the size of the empty storage room and the proposed date/time of the application. The applicator will apply the product using the proprietary delivery system developed by AgroFresh Inc. After the 24-hour application period, the AgroFresh applicator will return to the storage room and retrieve the delivery system after the room has been vented according to label directions.

Although potential exposure from applying SmartFresh™ is expected to be minimal, there is a potential for exposure to bystanders from potential leaks in the treatment area as well as workers re-entering the treatment area following application of 1-MCP to remove the generator or workers working in the vicinity of the treatment area. This potential exposure is expected to be intermittent and short-term to intermediate-term in duration.

3.5.1 Occupational exposure and risk

3.5.1.1 Handler exposure and risk

SmartFresh™ Technology is applied to the treatment area by a trained AgroFresh applicator. The appropriate amount of 1-MCP formulated as a powder is prepackaged in a water soluble pouch. The 1-MCP gas is released from the generator by turning the generator on, adding water and adding the water soluble pouch. There is a five-minute delay from the time the generator is started to the time the 1-MCP gas is released. It is expected that within this five-minute period the applicator will exit the treatment area and seal the treatment area to prevent entry during the 24-hour application time. There is potential for dermal exposure to the end use product (powder formulation) from handling the water soluble pouch. However, exposure and risk are expected to be minimal due to its packaging, the use of personal protective equipment (gloves) when handling the pouch and its low acute dermal toxicity. Applicators are not expected to be exposed to the gas, since there is a delay before gas formation.

3.5.1.2 Postapplication exposure and risk

The applicant submitted two studies that examined ambient air concentrations of 1-MCP inside and outside the treatment area during application and ventilation. These studies are entitled “1-MCP Venting and Determination of Residual 1-MCP in Release Water” and “1-MCP Release and Vent Studies”.

In the study entitled “1-MCP Venting Study and Determination of Residual 1-MCP in Release Water”, ambient air concentrations of 1-MCP were determined during application and ventilation of SmartFresh™ Technology to an immobilized trailer. Samples were collected from three locations inside the trailer at 1, 2 and 3 hours after the generator was started. Shortly after 3 hours, the refrigeration system in the trailer was activated to start circulation of air within the trailer. With the refrigeration and its associated circulation system on, the trailer doors were opened and venting samples were taken at three locations outside the trailer doors at approximately 0 minutes, 15 minutes and 30 minutes after opening the doors. Samples were also taken inside the centre of the trailer at 15 and 30 minutes. Samples inside the trailer were taken from the left bottom rear, centre and right top front. Samples outside the trailer were taken from the centre, 0.5 m from the trailer, and aligned either with the right or left side of the trailer, 1.5 m back.

In the study entitled “1-MCP Release and Vent Studies”, ambient air concentrations of 1-MCP were measured inside and outside 2 controlled atmospheric rooms containing 40 bins of apples during application and ventilation. The rooms were treated with 1-MCP for 12 or 24 hours. Single samples were collected inside the storage room and single samples were collected outside the storage room at the doorway and 3 m from the door in the hallway. Samples were collected at 0, 1, 4, 8 and 12 hours following application of 1-MCP and at 0, 15 and 30 minutes following the commencement of ventilation. An additional 24-hour sample was collected inside the storage room for the 24-hour 1-MCP application.

There were limitations in the quality assurance and quality control (QA/QC) procedures in both of the above-noted studies. For the “1-MCP Release and Vent Studies”, there were only two travel recovery samples, which demonstrated approximately 95% recovery. There were no other field recovery, travel recovery or storage stability samples prepared or analysed for either study. This is considered to be a major limitation and lowers the confidence in the reported data for the above-noted studies.

Despite the limitations in the two submitted studies, the results of the studies were consistent in that the target application rate was obtained during application in both studies, the peak 1-MCP concentration was obtained upon commencement of ventilation (range from 0.07–0.54 ppm) and 1-MCP concentrations were below the LOQ at all locations 15 minutes following the commencement of ventilation.

To approximate inhalation exposure to individuals re-entering the treatment area, a conservative approach was taken due to the limitations in the above-noted studies, mainly the lack of adequate QA/QC procedures. It was assumed that individuals would be exposed to the maximum value measured in the study (0.54 ppm, “1-MCP Venting Study and Determination of Residual 1-MCP in Release Water”, measured in the centre of the trailer upon commencement of ventilation) for 15 minutes and that the same individual would be exposed to 1-MCP concentrations of ½LOQ (0.0063 ppm) for the remainder of the day (7.75 hours). Postapplication exposure calculations are summarized in Table 3.5.1.2.1.

Table 3.5.1.2.1 Postapplication risk assessment

1-MCP concentration (ppm)	1-MCP concentration (mg/m^3)[a]	Inhalation rate (m^3/hr)[b]	Duration of exposure (hr)	Exposure (mg/kg bw/day)[c]	NOAEL (mg/kg bw/day)[d]	MOE
0.54	1.19	1	0.25	0.00425	9	2118
0.0063	0.0139	1	7.75	0.00154	9	5844
Total daily exposure:				0.00579	9	1554

[a] 1 ppm of 1-MCP is equivalent to 2.2 mg of 1-MCP per m^3. This was calculated using the density of 1-MCP of 2.2 g/L and the ideal gas law. Therefore, values expressed in ppm were converted to mg/m^3 by multiplying by 2.2.

[b] Inhalation rate is for light activity, short- to intermediate-term exposure, USEPA (1997) *Exposure Factors Handbook*.

[c] Exposure was calculated using the following formula:

$$\frac{\text{air concentration (mg 1-MCP/m}^3\text{)} \times \text{inhalation rate (m}^3\text{/hr)} \times \text{duration of exposure (hr)}}{\text{body weight (70 kg)}}$$

[d] NOAEL from the 90-day rat inhalation study, target MOE of 1000

These margins of exposure are considered to be acceptable. This assessment is considered to be conservative since it is unlikely given the rapid degradation of 1-MCP that an individual would be exposed to the peak value for 15 minutes and that the same individual would be exposed to ½LOQ for the remainder of the day.

Although the use of the limited air monitoring data from the submitted studies was considered to be appropriate for this use scenario, it should be noted that any expansions of use for 1-MCP may require the submission of an additional air monitoring study. This air monitoring study will have to include proper QA/QC procedures as outlined in the PMRA Regulatory Proposal PRO98-04, *Postapplication Exposure Monitoring Test Guidelines*, dated 4 September 1998.

3.5.2 Residential exposure and risk

3.5.2.1 Handler exposure and risk

There are no domestic products; therefore, a residential handler assessment was not required.

3.5.2.2 Postapplication exposure and risk

There is no postapplication exposure associated with the use of this product; therefore, a residential postapplication assessment was not required.

3.5.3 Bystander exposure and risk

For the proposed commercial use scenario, bystander exposure during and after application was considered minimal compared to re-entry worker scenarios and, therefore, not quantified.

4.0 Residues

4.1 Food residue summary

Analytical methodology in plant matrices
Acceptable method validation was submitted for the GC/FID method (Report AF-01-173) proposed for the enforcement of maximum residue limits of 1-MCP in apple. Validation data were included for determination of the parent compound, using external standard quantitation. A successful ILV was completed using apple. The LOQ was reported to be 0.01 ppm.

Analytical methodology in animal matrices
An analytical method for the determination of 1-MCP residues in meat and milk was not required based on the expectation that residues of 1-MCP in treated feed (<0.01 ppm) will not transfer into animal matrices.

Nature of the residue in animals
Based on the apple residue data, residues of 1-MCP detected in apples stored at 0–25.6°C, treated at 1.2 ppm (volume per volume [v/v]) for up to 7 days and sampled 0 to 336 hours following venting did not exceed 0.01 ppm. Although treated apple pomace may be fed to livestock, the intake of 1-MCP residues is expected to be less than 0.01 mg/kg total diet resulting in minimal transfer into meat and milk. Therefore, a ruminant metabolism study was not required.

Apple pomace is not a recognized poultry feed item. Therefore, a poultry metabolism study was not required.

Nature of the residue in plants
Four varieties of apple (Red Delicious, Gala, Granny Smith and Fuji) stored in an airtight treatment chamber, maintained at 03°C or ambient temperature (19.4–25.6°C), were treated with ^{14}C-1-MCP (radiochemical purity of 94.9%, specific activity of 87.0 mCi/mg) at a concentration of 1.2 ppm (v/v) for 24 hours. An additional experiment was conducted with Red Delicious apples stored at 0–3°C and treated for 7 days. After all treatments, the chamber was vented with air at a flow rate of 40 L/minute for 15 to 30 minutes and resealed. A sample set (one apple from the top, bottom and middle of the stack) was collected randomly at various times (0 to 336 hours) after venting and analysed for total radioactive residues.

Apples were homogenized with saturated ammonium sulfate solution. After the head space was sampled, the homogenate was further blended to reduce the particle size, and filtered. The radioactive residues in head space and filtrate were analysed by liquid scintillation counting (LSC), and the residue in filter cake was analysed by combustion/LSC. The total radioactive residues (TRRs) in all treated apples ranged from 0.00114 to 0.00911 ppm. The majority of the TRRs (63–100 %; 0.00114–0.00911 ppm) were detected in the filter cake, presumably due to the degradation of 1-MCP and subsequent incorporation of ^{14}C-residues in natural plant constituents. The TRRs in the head space and the filtrate accounted for ≤11.4% of the TRRs (≤0.00044 ppm) and ≤25.2% of the TRRs (≤0.00099 ppm), respectively. The TRRs were generally higher, ranging from 0.00656 to 0.00775 ppm, in Red Delicious apples stored at 0–3°C, treated for 7 days and analysed 0 to 48 hours after venting.

A reduction in TRRs as a function of time was more frequently observed in apples stored at 0–3°C and treated for 24 hours compared to the same treatment interval at ambient temperature. Also, this decrease in TRRs was most apparent in apples collected from the bottom of the stack, at both temperature ranges. Since the TRRs were all <0.01 ppm, further characterization/identification was not conducted.

Confined rotational crops and field accumulation in rotational crops
SmartFresh™ Technology (containing 1-MCP) is a plant growth regulator proposed for use as a postharvest treatment on stored apples to delay ripening. Therefore, based on its use pattern, confined and field accumulation in rotational crops were not required.

Supervised residue trials
The metabolism study was used to support the crop field trial requirement. A total of 8 trials were conducted on 4 varieties (Red Delicious, Gala, Granny Smith and Fuji) of apple stored in an air tight chamber maintained at temperature settings of 0–3°C or 19.4–25.6°C (ambient). Apples were treated with ^{14}C-1-MCP gas at a concentration of 1.2 ppm (v/v) for 24 hours. An additional trial was conducted on Red Delicious apples stored at 0–3°C and treated with ^{14}C-1-MCP for 7 days. Following all treatments, the chamber was vented for 15 to 30 minutes with air at a flow rate of 40L/minute. A sample set (one apple from the top, middle and bottom) was randomly collected at intervals of 0 to 336 hours after venting.

According to the data presented, a reduction in TRRs was more frequently observed in apples treated for 24 hours at 0–3°C compared to the same treatment interval at ambient temperature. Also, a decrease in TRRs was most apparent in apples collected from the bottom of the stack. The TRRs were generally higher in apples (Red Delicious) treated for 7 days at 0–3°C compared to the same variety of apple treated for 24 hours at 0–3°C.

Storage stability
Due to the volatility and reactivity of 1-MCP, apple samples collected from the residue trial were not frozen after sampling but were processed for analysis the day of sampling. Therefore, freezer storage stability data was not required.

Processing studies
The apple residue data demonstrated that when stored at 0–3°C or 19.4–25.6°C, treated at 1.2 ppm (v/v) for 24 hours or 7 days and sampled 0 to 336 hours after 15 to 30 minutes of venting, residues of 1-MCP in mature apples did not exceed 0.01 ppm. Therefore, processing studies were not required based on the expectation that measurable residues will not be observed in apple processed commodities such as juice and sauce.

Livestock feeding
No quantifiable residues of 1-MCP above the LOQ (0.01 ppm) were found in apples (maximum residue of 0.0091 ppm, n=60) stored in an air tight treatment chamber maintained at 0-3°C or ambient temperature, treated at 1.2 ppm (v/v) for 24 hours or 7 days and sampled 0 to 336 hours after a ventilation period of 15 to 30 minutes. Accordingly, when treated apples are processed, no measurable residues of 1-MCP are anticipated in various commodities including juice, sauce and pomace. Exposure of ruminant animals to treated apple pomace is not expected to result in a measurable transfer of 1-MCP residues into meat and milk. Therefore, a dairy cattle feeding study was not required.

Apple pomace is not a recognized poultry feed item; therefore, a laying hen feeding study was not required.

Dietary risk assessment
Since 1-MCP is a volatile gas and all matrices measured (including stored apples) had no measurable residues, the proposed use of SmartFresh™ Technology (containing 3.3% w/w 1-MCP) as a postharvest treatment intended to delay the ripening of mature stored apples does not pose an unacceptable dietary risk to any segment of the population, including infants, children, adults and seniors. As well, there is negligible concern regarding the 3-chloro-2-methylpropene (CMP) impurity, as the level in the EP is very low (0.000561%).

5.0 Fate and behaviour in the environment

Fate and behaviour in the environment are summarized in Appendix III.

5.1 Physical and chemical properties relevant to the environment

1-MCP was estimated to be very soluble (137 mg/L at 20°C), with no effect attributed to pH. However, based on the methodology of the solubility study and the nature of the compound, the results for solubility are difficult to interpret. The vapour pressure of 1-MCP indicated that the compound would be considered of very high volatility (2.5×10^5 Pa). The Henry's law constant of 1-MCP indicated that the chemical will have potential to volatilize from water and moist surfaces (4.37×10^9 Pa). The *n*-octanol–water partition coefficient for 1-MCP was negligible based on chemical structure. As the chemical is a volatile gas, there is negligible potential for bioaccumulation. The pK_a was not reported since 1-MCP is an unsaturated aliphatic hydrocarbon and, as such, does not

contain functional groups capable of dissociation in water. The UV–visible absorption spectrum of 1-MCP indicated that the compound has negligible potential to phototransform at environmentally relevant wavelengths of light (maximum absorption at $\lambda < 240$ nm; negligible absorbance at $\lambda = 290$ nm).

5.2 Abiotic transformation

1-MCP gas is generated by dissolving an 1-MCP/alpha cyclodextrin complex in water. Due to its high vapour pressure and as reflected by its Henry's law constant, the resulting 1-MCP gas quickly volatilizes from water. Once 1-MCP is vented to the atmosphere after use, the primary route of transformation will be via atmospheric reactions with ozone and hydroxyl (OH) radicals. Using a relevant 12-hour atmospheric OH exposure period and ozone concentrations of 1×10^{11} molecules/cm^3, the 1-MCP half-life is 0.123 and 0.027 days for OH radical and ozone reactions, respectively, based on the Atkinson model. The laser photolysis half-life of 1-MCP in the presence of hydroxyl radicals was 4.4 hours.

There are two environmental issues with the use of 1-MCP: 1) the production of ozone, and 2) the production of formaldehyde (USEPA List 1 substance). Atmospheric oxidation and self reaction of 1-MCP leads to the production of ten ozone molecules, similar to that of propene. Based on the estimated production of 0.5 tons 1-MCP/year, the registrant concluded that the amount of ozone produced from apple storage facilities would be negligible compared to that produced from volatile organic chemicals (VOCs) from burning of fossil fuels. Formaldehyde is also formed from the degradation of 1-MCP in the atmosphere. The registrant claimed that 0.28 tonnes of formaldehyde may be formed globally from industrial sources and combustion, but in the context of the world production of formaldehyde (12 000 000 tonnes), the amount produced from MCP is negligible. Formaldehyde is also not persistent in the environment.

Atmospheric abiotic transformation is expected to be an important route of transformation for 1-MCP.

5.3 Biotransformation

Data are not required.

5.4 Mobility

Data are not required.

5.5 Terrestrial field dissipation

Data are not required.

5.6 Bioaccumulation

Data are not required.

5.7 Summary of fate and behaviour in the terrestrial environment

Due to its high vapour pressure and as reflected by its Henry's law constant, 1-MCP gas quickly volatilizes from water. In the atmosphere, the primary route of transformation of 1-MCP will be via reactions with ozone and hydroxyl radicals (half-lives are 0.027 and 0.123 days, respectively). The laser photolysis half-life of 1-MCP in the presence of hydroxyl radicals was 4.4 hours.

The production of ozone and formaldehyde during atmospheric reactions of 1-MCP will be negligible.

Atmospheric abiotic transformation is expected to be an important route of transformation for 1-MCP.

5.8 Summary of fate and behaviour in the aquatic environment

Based on the vapour pressure and Henry's law constant for 1-MCP, volatilization from water is a more important route of dissipation than hydrolysis. The concentration of 1-MCP in the aquatic environment is expected to be negligible as it is a volatile gas product and preferentially partitions from the water into the atmosphere.

5.9 Expected environmental concentrations

There will be no exposure of the environment to 1-MCP during use as it is to be used indoors in air-tight chambers as a postharvest treatment on apples. However, exposure will occur once treatment rooms are vented. The maximum release of 1-MCP would be 1 ppm after venting based on the maximum application rate, applied once per year in a closed apple storage facility in late summer (August to October). Based on its rapid oxidative half-life (4.4 hours based on the laser photolysis study), 1-MCP is expected to be present at negligible concentrations in the air, soil, aquatic systems as well as on vegetation and other food sources. Given its high volatility and Henry's law constant, 1-MCP is not expected to remain in the aquatic environment if deposition and/or drift of the vapour to aquatic systems occurred.

6.0 Effects on non-target species

6.1 Effects on terrestrial organisms

Application of SmartFresh™ Technology to apples will take place after they are harvested and under closed conditions in storage facilities between late August and late October. The exposure of honeybees, most beneficial predators and nesting birds to 1-MCP from

atmospheric deposition in the immediate area is negligible based on timing of application and its rapid oxidation half-life (4.4 hours). Data are not required.

6.2 Effects on aquatic organisms

Data are not required.

6.3 Effects on biological methods of sewage treatment

Data are not required.

6.4 Risk characterization

1-MCP is to be used indoors as a postharvest treatment on apples; therefore, there will be no exposure of the environment during use. However, exposure will occur once treatment rooms are vented after use. The maximum release of 1-MCP would be 1 ppm after venting based on the maximum application rate, applied once per year in a closed apple storage facility in late summer. Based on its short atmospheric half-life (4.4 hours) and timing of application, 1-MCP is expected to pose negligible risk to aquatic and terrestrial organisms.

6.5 Risk mitigation

1-MCP is used indoors and is non persistent in the terrestrial and aquatic environment once vented to the atmosphere. Thus, the risk to terrestrial and aquatic organisms is expected to be negligible.

7.0 Efficacy

7.1 Effectiveness against target organisms or with respect to the effect achieved

7.1.1 Intended use

SmartFresh™, containing 3.3% 1-MCP, is intended for use on stored pome fruit to increase fruit storage life. It is specifically proposed for application at a maximum 1-MCP rate (concentration) of 1.0 ppm (v/v in air) in enclosed gas-tight areas immediately after harvest, prior to storage, prior to shipment and/or just prior to sale, provided that application is made within two weeks of harvest and before the climacteric peak in respiration. It is specifically claimed to maintain firmness, maintain titratable acidity, prevent superficial scald, prevent soft scald, reduce internal ethylene production, protect from external sources of ethylene, reduce fruit respiration, delay ripening and senescence,

reduce incidence of peel greasiness in apples, reduce incidence of core flush and mealiness and reduce chilling injury. The rate proposed is the same as that registered in the US, but higher than that supported in the European Union where it is registered in some member countries, including the United Kingdom (UK) at an average rate of 0.625 ppm.

SmartFresh™ is proposed for application in enclosed areas that include storage rooms, greenhouses, coolers, shipping containers, enclosed truck trailers, or ambient temperature, refrigerated or controlled atmosphere food storage facilities. Treatment was originally proposed at a temperature of at least 13°C; however, the applicant subsequently stated that application temperature is intended to range from 0°C to room temperature. Application is to be made by means of a proprietary generator device within which one water-soluble packet containing the product is placed. This device is placed in such a manner that it is within the airflow of the internal refrigeration system of the enclosed room in which it is applied. The active ingredient, 1-MCP, is released as a vapour upon addition of water to the device, and is circulated throughout the storage area for 24 hours. There are 11 soluble package sizes that range from 34.0 to 310.6 g product for treatment of room volumes that range from 500 to 5400 m^3. The specific concentration of 1-MCP achieved is a function of the size of the soluble packet and the specific volume of the treatment room, so that 1-MCP can be delivered at concentrations ranging from approximately 0.725 to 1.0 ppm. Treated fruit not destined for immediate marketing are then stored in accordance with standard commercial practices that include low temperature (refrigerated) air and controlled atmosphere.

The claims proposed for SmartFresh™ are summarized in Table 7.1.1.1.

Table 7.1.1.1 Claims proposed for SmartFresh™ when applied to harvested pome fruit at a 1-MCP concentration of 1.0 ppm in accordance with the draft label, dated 20 February 2003

Proposed claims	
Host	**Pome fruit**
Use directions:	
Application rate	1.0 ppm (maximum)
Application duration	24 hours
Application temperature	Cool (13°C) and warm (above 13°C)
Application window	Within 2 weeks after harvest
Application number	One, with possibility of a repeat before sale

Proposed claims	
Application equipment	Use of a proprietary device to deliver 1-MCP into the treatment room
Sites	Enclosed areas, such as storage rooms, coolers, greenhouses, enclosed truck trailers, shipping containers, and ambient temperature, refrigerated or controlled atmosphere food storage facilities
Storage regime	Refrigerated air (up to 6 months) or controlled atmosphere (over 6 months)
Efficacy claims:	
Maintaining fruit firmness	
Reducing internal ethylene production	
Reducing respiration	
Delaying in ripening and senescence	
Preventing superficial scald on pome fruit	
Maintaining titratable acidity	
Protecting from external sources of ethylene	
Preventing soft scald on pome fruit	
Reducing incidence of peel greasiness	
Reducing mealiness in pome fruit	
Reducing chilling injury	

7.1.2 Mode of action

The active ingredient, 1-MCP, is claimed to compete with ethylene at membrane-bound ethylene receptor proteins within the fruit, thereby inhibiting both the action of ethylene and the synthesis of additional ethylene via a positive feedback mechanism from the ethylene-receptor complex. The inhibition of ethylene action and synthesis delays the onset of the climacteric period of fruit ripening in which ethylene production and respiration increase rapidly. The maturation of the fruit is therefore delayed, with the result that fruit remains firmer and maintains its acidity for a longer period.

7.1.3 Crops

Proposed crop claims were stated as 'pome fruit', which in Canada includes crops such as apples, pears and quince fruit. Specific claims were made for apples.

7.1.4 Effectiveness against pests

7.1.4.1 Effectiveness in maintaining fruit firmness

The climacteric phase of ripening is characterized by accelerated fruit softening, water loss and loss in acidity. Excessive loss in fruit firmness decreases consumer acceptance and, therefore, marketability. The claim that SmartFresh™ maintains flesh firmness of fruit destined for immediate marketing or storage in either refrigerated air or in a controlled atmosphere is the principal claim for this product.

In support of the claim that SmartFresh™ maintains fruit firmness, data were submitted from small-scale efficacy studies conducted over five harvest-storage seasons, from 1998–1999 until 2002–2003. Trials were conducted in Ontario, British Columbia and Washington state. In trials initiated in Ontario in 1999–2000, 1-MCP (Ethylbloc, labelled as containing 0.43% 1-MCP) was applied at rates (concentrations) of up to 0.6 ppm 1-MCP. In trials initiated in 2000, 1-MCP (SmartFresh™, labelled as containing 0.14% 1-MCP) was applied at a maximum concentration of 0.6 ppm. In trials initiated in 2001, 1-MCP (SmartFresh™, labelled as containing 0.14% 1-MCP) was applied at a maximum concentration of 1.0 ppm. In trials conducted in British Columbia, the same formulation of SmartFresh™ (0.14% 1-MCP) was applied at 0.075 to 3.9 ppm, with the selection of concentrations tested being specific to trial. An unspecified formulation of SmartFresh™ was applied at 0.5 and 1.0 ppm in the Washington state trial. Laboratory equipment was used to deliver 1-MCP in all trials.

The actual concentration of 1-MCP applied in experiments prior to 2000 is in doubt due to conflicting information. In trials conducted in Ontario prior to the 2000–2001 storage season, it was reported that the concentration of the formulation used, Ethylbloc, was 60% that of the labelled guarantee of 0.43%, or about 0.26%. However, the following was reported.

> "After AgroFresh Inc. acquired the technology from Floralife Inc. for food use, it was discovered through analytical chemistry studies that the formulation actually contained 0.14% of 1-MCP and not the 0.43% thought to be present by Floralife, Inc. This change in concentration was reported to the USEPA and to Researchers [*sic*] around the world who had conducted studies with the product with the understanding that it contained 0.43% 1-MCP."

The applicant did not clarify whether the difference between 0.26% and 0.14% was due to variation in active concentration between batches. The maximum concentration intended to be tested in the trials conducted in Ontario in the 1999-2000 storage season was 1.0 ppm; however, based on the above correspondence, the maximum concentration actually tested was 0.6 ppm. The formulation of SmartFresh™ tested in the 2000–2001 storage season and later was identified to contain 0.14% 1-MCP. It was reported that this was verified by gas chromatography. The reported rates in these later trials (those conducted in the 2000–2001 storage season and later) would therefore appear to be correctly identified.

Data from 20 trials conducted in Ontario at the University of Guelph over four storage seasons (1998–1999 until 2001–2002) were considered in support of the claim that SmartFresh™ maintains fruit firmness. A rate (concentration) series trial was initiated in 1998. In 1999, nine trials were initiated to evaluate 1-MCP concentration of up to 0.6 ppm for air storage (five trials) or controlled atmosphere storage (four trials), and in one trial in 2000 in both air and controlled atmosphere storage. Two trials were initiated in 1999 to evaluate the effect of treatment temperature and treatment time. Response among cultivars was investigated in two trials, one initiated in 2000 and the other in 2001. The effect of harvest date on the efficacy of 1-MCP was evaluated in two trials initiated in 2000. The effect of treatment delay after harvesting was investigated in one trial initiated in 2000. The effect of a preharvest application of the plant growth regulator, ReTain (aminoethoxyvinylglycine hydrochloride), on the efficacy of 1-MCP was investigated in three trials initiated in 1999, 2000 and 2001. Fruit firmness following storage under standard controlled atmosphere conditions was assessed in all three trials. The trial initiated in 1999 also included evaluation following refrigerated air storage. In the trial initiated in 2001, the effect of diphenylamine (DPA) and a CO_2-free atmosphere on 1-MCP performance was also investigated. Products containing DPA may be used on apples for scald control. The CO_2-free atmosphere treatment was included in this trial to assess its potential to eliminate CO_2-induced injury.

Data from nine trials conducted in British Columbia over three storage seasons (2000–2001 to 2002–2003) were considered in support of the claim that SmartFresh™ maintains fruit firmness. In these trials, concentrations of 1-MCP ranging from 0.075 to 3.9 ppm were evaluated; none included treatments of 1-MCP at the proposed maximum rate of 1.0 ppm (range of 0.725 to1.0 ppm). Following treatment, fruit were stored in either refrigerated air or controlled atmosphere conditions.

Data were submitted from one trial that was conducted in Washington state in which four separate lots of Red Delicious apples were treated with SmartFresh™ at 0, 0.5 and 1.0 ppm 1-MCP, following which the fruit were stored in refrigerated air or controlled atmosphere conditions.

Fruit firmness measurements were made on both (red and green) sides of the fruit using an Effegi penetrometer fitted with an 11 mm tip.

Application concentration (rate)

There were 25 trials in which multiple rates were evaluated. Some of these trials included efficacy assessment of 1-MCP on fruit stored in separate treatments of refrigerated air and controlled atmosphere and in some trials, more than one apple cultivar was assessed. In these 25 trials, a fruit firmness response to 1-MCP was observed in a total of 50 trial–cultivar–storage regime combinations. The lowest effective rate could be ascertained in only 14 of these 50 combinations.

There were too few data points (trial–cultivar–storage regime combinations) in which there was evidence that the proposed rate of maximum 1.0 ppm was more efficacious than 0.6 ppm. However, the applicant submitted the following rationale for the registration of SmartFresh™ Technology in Canada at the proposed maximum use rate of 1.0 ppm:

> "There are a limited number of trials in the dossier that was submitted to the UK that compare the results from a 625 ppb to a 1000 ppb dose. The results of these trials do not show a significant difference between the two doses. Despite the results of these trials, we feel strongly that the use rate we are recommending for the US and Canada (1000 ppb, max) is the appropriate use rate that will ensure the customer receives the full benefits of SmartFresh™. The US and Canadian markets have some fundamental differences to the UK market. In addition to the longer storage times of fruit, the US and Canada are also major exporters of apples to overseas markets versus the UK who is a small exporter and only to other European markets. These overseas exports produce further stress on the fruit after storage and also benefit from SmartFresh™ treatment to maintain firmness. Remember that SmartFresh™ is applied at an extremely low use rate - approximately 5 grams of active ingredient treats approximately one million pounds of apples. Because of the extremely small amount of active ingredient involved in a treatment, there is not a lot of room for error. There are numerous factors that could adversely affect the treatment results, such as air-tightness of the treatment room, variety of the fruit, maturity of the fruit at harvest, time from harvest to treatment, length of storage, conditions of storage and transportation time to distant markets following storage. In order to ensure that the product provides consistent, high performance in light of these factors, we recommend the treatment rate of 1000 ppb, max be accepted."

It was indicated by the applicant that apples grown in Canada are stored for up to 11 months, longer than the typical maximum storage period of six months in the UK, and that this difference in storage period was a reason for the difference between the UK rate of 0.625 ppm and the proposed Canadian rate of 1.0 ppm. The applicant argued that a two-rate structure based on length of storage, one for 6 months or less, and one for greater than 6 months was not practical since packers and shippers do not know in advance when

apples in storage will be marketed, since time of marketing is based on market demand and pricing.

The data submitted conditionally support a claim of fruit firmness maintenance at the proposed maximum 1-MCP rate of 1.0 ppm. Additional data are required to support the proposed rate.

Cultivar response

Two trials were conducted in Ontario to assess fruit firmness response among several cultivars of different maturity groups to 1-MCP. Apples of 13 cultivars were harvested at 4 locations in 2000, with one location per cultivar, and apples of the same 13 cultivars plus two very early season cultivars were harvested in Norfolk County in 2001. Harvest dates varied in accordance with cultivar maturity. Fruit were treated with 0, 0.3 and 0.6 ppm 1-MCP in the first trial and with 0 and 1.0 ppm in the second. Fruit firmness was evaluated one day and week following storage in refrigerated air for approximately 60, 120 and 150–180 days in the trial initiated in 2000 and for approximately 90 and 150 days in the one initiated in 2001, except for the two very early season cultivars that were assessed following 47 and 94 days of storage.

Response varied by cultivar in each trial. The very early season cultivars Sunrise and Gingergold included only in the trial initiated in 2001 had a low response to 1-MCP. In the early season cultivar category, Honeycrisp exhibited no response in either year, and McIntosh showed a low response after a 180-day storage period in the first year and a low response following either 90 or 150 days of storage in the second year. However, McIntosh showed a greater response to 1-MCP in other trials. A more consistent response was shown for the remaining early season cultivar Gala. Fruit of the mid-season cultivars Empire, Spartan and Jonagold was more consistent in their response to 1-MCP between trials than that of Cortland and Golden Delicious. In the late season cultivar category, fruit of Ida Red had the greatest response to 1-MCP, followed by Fuji. The three remaining late-season cultivars, Red Delicious, Mutsu and Northern Spy were less consistent in their response between trials. Despite the varying degrees of sensitivity among cultivars, the applicant indicated that one application rate was appropriate for use on apples of all cultivars since apples of multiple cultivars are often placed in a single storage room, particularly for smaller growers and packers. Furthermore, it was indicated that field growing conditions and harvest maturity could affect the response of a particular cultivar. Establishing a multiple rate structure based on cultivar sensitivity was therefore deemed by the applicant to be impractical.

The data support use of 1-MCP on a range of cultivars; however, a statement must be included on the label to indicate that response to 1-MCP can be expected to vary among cultivars.

Length of storage period

The applicant explained that the proposed 1-MCP rate of 1.0 ppm is required to maintain firmness and, therefore, marketability of fruit that may be stored for up to 11 or more

months prior to marketing. This is the principal reason for the proposed application rate being greater than the rate of 0.625 ppm registered in the UK, where apples are typically stored for up to six months, as indicated by the applicant. Fruit firmness data were reported for up to 8 months in Ontario trials and 9 months in British Columbia and Washington state trials. Use of 1-MCP for fruit firmness maintenance for periods of up to nine months is considered supported.

Treatment temperature and duration

In a trial initiated in 1999, Empire and Cortland apples treated with 0.6 ppm 1-MCP achieved maximum fruit firmness response after 3 and 6 hours of treatment, respectively, at either 13 or 23°C. Since fruit were equilibrated to a temperature of 20°C prior to treatment, it appears that much of the 1-MCP was absorbed by the fruit within the first few hours, before the temperature reached either of the designated temperatures. Maximum fruit firmness response was achieved in the 3°C treatment after 6 hours for Empire and 9 hours for Cortland, indicating that temperature does affect rate of 1-MCP absorption into the fruit. In a cultivar response trial initiated in 2001 in Ontario, 1-MCP was applied at a temperature of 0°C over 24 hours. Response varied depending on cultivar, with some cultivars (Empire, Ida Red and Mutsu) showing a fruit firmness response of over 20%, but generally less than 30%. This higher response was less than that observed in the cultivar response trial initiated in 2000 in which application took place at 20°C. It is not clear whether this somewhat lower response was due to treatment temperature or environmental effects, given that in another trial initiated in 2000 on McIntosh apple (a cultivar that usually exhibits a low to moderate response to 1-MCP), treatment at 3°C for 24 hours after 3 days holding at that same temperature resulted in a greater fruit firmness response than a 3-day holding temperature and 24 hour treatment temperature of 13°C. Data from trials conducted in British Columbia indicated that treatment at 0°C with 1-MCP resulted in greater fruit firmness at up to 9 months storage than the untreated control fruit, although treatment was for 48 hours, which is twice the proposed treatment time. Overall, there are sufficient data to support application at a temperature ranging from 0 to 23°C over a 24 hour treatment period.

Harvest date

Several trials were conducted to examine the effect of two or more harvest dates on the efficacy of 1-MCP on fruit firmness. In two trials initiated in Ontario in 1999, Delicious and McIntosh fruit from the second harvest exhibited a much greater response to the reported concentration of 0.6 ppm 1-MCP when evaluated after 60–180 days of storage in air at 0–1°C than fruit harvested approximately one week earlier. The maturity status of the fruit at each of the two harvest dates was not indicated. In a trial initiated in 2000 in which McIntosh apples were harvested at optimum maturity, as well as one week before and one week after, the greatest fruit firmness response to 0.6 ppm 1-MCP was observed for fruit harvested at optimum maturity and evaluated after 75 days of storage in air at 0–1°C, or harvested one week earlier and evaluated after 150 days (about 5 months) of storage in air. For fruit stored under controlled atmosphere conditions for 150 days, the greatest response was for early harvested fruit. In another trial initiated in 2000, Empire apples harvested on two dates five days apart and treated with 1-MCP exhibited a similar

fruit firmness to 1-MCP applied at either 0.06 or 0.6 ppm. Overall the data suggest that maximum response to 1-MCP treatment can be expected when apples are harvested at optimum maturity, or up to one week earlier, and stored in either air or controlled atmosphere.

Postharvest application window (number of days after harvest at which fruit can be treated)

In one study conducted with McIntosh apples in which the effect of treatment delay was investigated at holding/treatment temperatures of 3 and 13°C, the greatest fruit firmness response, when evaluated after 45 days of storage at 0–1°C, was achieved where treatment was made as follows:

- at 13°C within one day after harvest (1-MCP-treated fruit were 31% more firm than untreated); or
- where treatment was made at 3°C within one day after harvest (1-MCP-treated fruit were 35% firmer than untreated); or
- where treatment was made at 3°C within 3 days after harvest to fruit that were cooled to that same temperature immediately after harvest (1-MCP-treated fruit were 42% more firm than untreated).

Fruit treated at 3 days or later at a temperature of 13°C, or 6 days or later at a temperature of 3°C had very little or no response to 1-MCP. Collectively, the data submitted support an application window of 0 to 3 days after harvest for fruit that are immediately cooled to 0–3°C following harvest with treatment being made within that temperature range, and up to 1 day following harvest for harvested fruit that are held and treated at temperatures greater than 3°C and up to 23°C.

Storage regime (refrigerated air vs. controlled atmosphere)

Two trials were conducted in which the effect of 1-MCP on firmness of apples stored in refrigerated air was compared to those stored in controlled atmosphere. In the trial initiated in 1999, the firmness of Empire fruit that was stored in controlled atmosphere for 140 days was greater than for fruit stored in refrigerated air for the same period. However, fruit stored in refrigerated air showed a greater relative response to 1-MCP treatment than fruit stored in controlled atmosphere, and it appeared that this was due to the greater effect of controlled atmosphere in maintaining firmness. In the trial initiated in 2000, the firmness of McIntosh and Delicious apples was greater for fruit treated with 0.6 ppm 1-MCP and stored in controlled atmosphere for 200 days than for fruit treated with this rate of 1-MCP and stored in refrigerated air for 120 days. Fruit stored in controlled atmosphere showed a greater relative response to 1-MCP treatment than that stored in refrigerated air in this trial. The data support the use of 1-MCP to apples destined for storage in either refrigerated air or controlled atmosphere.

Effect of preharvest treatments of ReTain and postharvest treatments of DPA

ReTain, containing aminoethoxyvinylglycine, may be used in apple orchards to reduce preharvest fruit drop. Products containing DPA may be used prior to storage to reduce superficial scald in apples during storage. Three trials were initiated in 1999, 2000, and

2001 to evaluate whether the efficacy of 1-MCP for firmness maintenance of Empire apples is affected by ReTain; the trial initiated in 2001 also included DPA treatment as a factor. ReTain did not affect the efficacy of 1-MCP applied at 0.6 ppm (trials initiated in 1999 and 2000) or 1.0 ppm (trial initiated in 2001) for firmness maintenance for fruit stored in standard controlled atmosphere in any of the three trials or refrigerated air in one trial. However, in the trial initiated in 2001 in which the effect of a CO_2-free atmosphere on the efficacy of 1-MCP was evaluated, fruit that were treated with ReTain were more firm than fruit that were not treated with ReTain, but only following 240 days of storage in a CO_2-free atmosphere. DPA appeared to have little effect on fruit firmness. Overall, ReTain and DPA would not be expected to affect product efficacy.

The proposed product, SmartFresh™ Technology containing 3.3% 1-MCP, can be recommended for a registration, conditional upon the submission of additional data to support the proposed rate of 1.0 ppm and the submission of data from operational trials in which the proposed formulation and the proposed application equipment are used.

7.1.4.2 Effectiveness in reducing internal ethylene production

Trials in which ethylene evolution or internal fruit ethylene concentration were measured were conducted on fruit harvested in Ontario in 1999, 2000 and 2001. In trials initiated in 1999, 1-MCP (Ethylbloc, labelled as containing 0.43% 1-MCP) was applied at rates (concentrations) of up to 0.6 ppm. However, as reported above, it isn't unequivocally clear whether the maximum concentration was 0.6 ppm or a lower concentration. In trials initiated in 2000 and 2001, 1-MCP (SmartFresh™, labelled as containing 0.14% 1-MCP) was applied at a maximum concentration of 0.6 and 1.0 ppm, respectively. In all trials, laboratory equipment was used to deliver 1-MCP.

Data were submitted from trials conducted in Ontario over three seasons in support of the claim that SmartFresh™ reduces ethylene production. In 1999, three trials were initiated to evaluate 1-MCP concentration of up to 0.6 ppm for non-refrigerated air storage (2 trials) and in both refrigerated air and controlled atmosphere storage (1 trial). The effect of SmartFresh™ on ethylene evolution from fruit of multiple cultivars was investigated in two trials initiated in 2000 and 2001. In the trial initiated in 2001, internal ethylene concentration was also evaluated after SmartFresh™ application and after 90 days of refrigerated air storage. The effect of treatment delay on ethylene evolution after harvesting was investigated in one trial initiated in 2000. The effect of a preharvest application of the plant growth regulator ReTain (aminoethoxyvinylglycine hydrochloride), DPA and a CO_2-free atmosphere was investigated in one trial initiated in 2001.

Generally, ethylene evolution was less for fruit treated with 1-MCP, although response varied by cultivar and storage regime. Greater levels of flesh softening were generally associated with greater levels of ethylene evolution and internal ethylene concentration. While the applicant has proposed a claim of reduced internal ethylene production, the actual effect of 1-MCP is to delay the rise in ethylene production during ripening.

Therefore, the data submitted support a claim of delayed rise in internal ethylene production for apples treated with 1-MCP.

7.1.4.3 Effectiveness in reducing fruit respiration

Trials in which respiration was measured were conducted on fruit harvested in Ontario in 1999, 2000 and 2001. In trials initiated in 1999, 1-MCP (Ethylbloc, labelled as containing 0.43% 1-MCP) was applied at rates (concentrations) of up to 0.6 ppm. However, as reported above, it isn't unequivocally clear whether the maximum concentration was 0.6 ppm or a lower concentration. In trials initiated in 2000 and 2001, 1-MCP (SmartFresh™, labelled as containing 0.14% 1-MCP) was applied at a maximum concentration of 0.6 and 1.0 ppm, respectively. In all trials, laboratory equipment was used to deliver 1-MCP.

Data were submitted from trials conducted in Ontario over three seasons in support of the claim that SmartFresh™ reduces respiration, measured as CO_2 production rate. In 1999, one trial was initiated to evaluate 1-MCP concentration of up to 0.6 ppm for non-refrigerated air storage. Also in 1999, two trials were initiated in which fruit CO_2 production was assessed following storage in refrigerated air and controlled atmosphere. The effect of SmartFresh™ on CO_2 production from fruit of multiple cultivars was investigated in two trials initiated in 2000 and 2001. Also in two trials initiated in 2001, fruit CO_2 production levels were evaluated over a two week period following refrigerated air storage for 0, 90 and 150 days. The effect of a preharvest application of the plant growth regulator ReTain (aminoethoxyvinylglycine hydrochloride), postharvest application of DPA and controlled atmosphere with or without CO_2 was investigated in one trial initiated in 2001.

Generally, respiration, measured as rate of CO_2 production, was less for fruit treated with 1-MCP, although response varied by cultivar and storage regime. Greater levels of flesh softening were generally associated with greater levels of CO_2 production. While the applicant has proposed a claim of reduced respiration, the actual effect of 1-MCP is to delay the rise in respiration during ripening. Therefore, the data submitted support a claim of delayed rise in fruit respiration for apples treated with 1-MCP.

7.1.4.4 Effectiveness in reducing effects from external sources of ethylene

No data were provided to assess this specific claim; therefore, it is not supported.

7.1.4.5 Effectiveness in delaying ripening and senescence

Application of 1-MCP can be expected to delay the rise in respiration and internal ethylene production that is associated with the climacteric phase of ripening. Ripening and senescence of fruit treated with 1-MCP can therefore be expected to occur later than in untreated fruit. The claim that ripening and senescence are delayed is supportable.

7.1.4.6 Effectiveness in preventing superficial scald on pome fruit

Scald is a general term that is applied to a group of skin disorders that can occur on susceptible varieties of apples and pears. There are various types of scald, including rugose scald, browning scald, lenticel spot scald, stem-end browning scald, sun scald, soft scald (also known as ribbon scald or deep scald), superficial (common) scald and senescent scald. All have characteristic traits that define them. Generally, scald is a brown or grey discolouration that forms in irregular patches on the fruit surface where the top layer of cells have died. The disorder becomes apparent on the fruit a few days after being removed from storage. It is believed that numerous factors will influence the extent (severity) of scald symptoms, including high temperatures and humidity at the time of harvest as well as maturity of the apple at time of harvest.

Data from eight trials conducted between 1999 and 2001 in which SmartFresh™ was tested for control of superficial scald were reviewed to assess this claim. Results show that treating apples with a single application of 1-MCP at 0.15 to 0.3 ppm and storing them under air or controlled atmosphere conditions for 110, 120 or 180 days did not provide consistent, effective control (prevention) of superficial scald on the majority of apple cultivars tested (McIntosh, Delicious, Northern Spy, Cortland and Spartan). However, if apples were harvested at optimal maturity and treated once for 18 to 24 hours with 1-MCP at 0.6 ppm (24 to 72 hours after harvest), acceptable levels of scald prevention were reached. This application rate resulted in the greatest number of apples with no scald, or slight (but still marketable) scald ratings, and the least number of unmarketable apples (due to scald damage). No commercial products were tested for comparison purposes. There were variations noted between the different varieties tested, which make generalizing across all apple varieties inaccurate.

The efficacy of 1-MCP at the proposed rate of 1.0 ppm for superficial scald prevention was assessed in only one trial conducted on Delicious apples. The 1-MCP treatment was compared to an untreated check. After either 90 or 150 days of refrigerated air storage (0°C) following which apples were removed and held for 7 days at ambient temperature, a similar proportion of marketable vs. non-marketable apples were observed for 1-MCP treated apples as compared to that observed in other trials for apples treated with 0.6 ppm 1-MCP. No direct comparisons could be made between 1-MCP rates of 0.6 and 1.0 ppm for superficial scald in any of the trials reviewed.

Data from five trials were compared in which either Delicious or McIntosh apples were treated with 0 or 0.6 ppm 1-MCP, then stored in either refrigerated air (0°C) or a controlled atmosphere (3°C, >95% relative humidity) for 75, 110, 120 or 150 days. Results show that for McIntosh apples, the controlled environment provided better storage conditions than refrigerated air for both treated and untreated apples. However, both storage methods are compatible with 1-MCP applications, since 1-MCP treatment resulted in less scald-affected apples being produced after storage, compared to apples that were not treated with 1-MCP.

7.1.4.7 Effectiveness in preventing soft scald on pome fruit

No data were provided to assess this specific scald claim, therefore it is not supported.

7.1.4.8 Effectiveness in reducing peel greasiness in apples

The incidence and severity of peel greasiness of Jonagold apples treated with 1-MCP at 0, 0.06, 0.3 or 0.6 ppm was assessed following storage in one trial. Fruit were treated at harvest (23°C for 18 hours), then stored in refrigerated air (0°C) for 60, 120 or 180 days. Apples were rated for peel greasiness in terms of no greasiness, slight greasiness (but fruit still marketable) or greasiness (unmarketable apples due to peel greasiness). It was not indicated on which assessment date (after 60, 120 or 180 days of storage) the single assessment for peel greasiness was made.

Application of 1-MCP appeared to reduce the incidence of peel greasiness of Jonagold apples in this trial; however, it was not specified when apples were rated or whether differences were statistically significant. Furthermore, data were limited to one apple cultivar in one trial. Therefore, additional data are required before this claim can be considered for registration.

7.1.4.9 Effectiveness in reducing the incidence of core flush in pome fruit

No data were provided that specifically assessed this claim; therefore, it is not supported.

7.1.4.10 Effectiveness in reducing the incidence of mealiness in pome fruit

No data were provided that specifically assessed this claim; therefore, it is not supported.

7.1.4.11 Effectiveness in reducing chilling injury

No data were provided that specifically assessed this claim; therefore, it is not supported.

7.1.5 Total spray volume

The total spray volume is not applicable as SmartFresh™ Technology is applied by means of a proprietary device that releases the active ingredient as a gas when water is added.

7.1.6 Effects on the quality of plants or plant products

N/A

7.1.7 Effects on transformation processes

N/A

7.1.8 Effects on the yield of treated plants or plant products

N/A

7.2 Phytotoxicity to target plants or to target plant products

No adverse effects were reported in or on fruit following treatment with 1-MCP, with the exception of external carbon dioxide injury. External carbon dioxide injury may occur on apples that are held in controlled atmosphere storage where CO_2 levels typically range from 2 to 4.5%. Injury may be affected by a number of factors, including type of cultivar, temperature, fruit maturity and seasonal growing conditions. Injury is typically manifested as roughened, bronze coloured lesions on the skin that can reduce marketability. An apple may be rendered unmarketable if more than a few small lesions are present.

Data were submitted from two trials in which the effect of 1-MCP on CO_2 injury was investigated following storage in controlled atmosphere conditions. In 1999, one trial was initiated to evaluate 1-MCP (Ethylbloc, labelled as containing 0.43% 1-MCP) concentrations of up to 0.6 ppm in controlled atmosphere storage. The effect of a preharvest application of the plant growth regulator, ReTain (aminoethoxyvinylglycine hydrochloride) in combination with 1-MCP (SmartFresh™, labelled as containing 0.14% 1-MCP) concentrations of up to 0.6 ppm was investigated in one trial initiated in 2000. In all trials, laboratory equipment was used to deliver 1-MCP.

The data indicate that 1-MCP may exacerbate CO_2 injury in controlled atmosphere storage, particularly for fruit that had received a preharvest treatment of ReTain. The results indicated that twenty percent or more of fruit treated with 1-MCP and stored in a controlled atmosphere may be unmarketable as a result of this disorder. It is recommended that the following warning statement be placed on the label: “Treatment with SmartFresh™ followed by controlled atmosphere storage may increase incidence and severity of CO_2 injury.”

7.3 Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation

7.3.1 Impact on succeeding crops

Data are not required. SmartFresh™ is proposed for use on pome fruit in storage and, therefore, would not impact on other crops.

7.3.2 Impact on adjacent crops

Data are not required. SmartFresh™ is proposed for use on pome fruit in storage and therefore would not impact on other crops.

7.3.3 Impact on seed viability

Data are not required. Apple trees are typically propagated by either budding or grafting.

7.3.4 Tank mixing recommendations

N/A

7.4 Economics

N/A

7.5 Sustainability

7.5.1 Survey of alternatives

The only alternative product registered to delay apple maturity and maintain fruit quality is ReTain Plant Growth Regulator (Registration Number 25609), with the active ingredient aminoethoxyvinylglycine hydrochloride (15% guarantee). This product is mainly marketed for use on apple trees to control preharvest fruit drop, with the lesser claims that it "may also delay fruit maturity, help maintain fruit quality (e.g. firmness) and may reduce the incidence and/or severity of watercore". The product is applied four weeks before the anticipated harvest date and, therefore, has a different use pattern than SmartFresh™.

For protection against storage scald, three products are registered in Canada:

- No Scald DPA EC-283, Registration Number 13471, containing a.i. diphenylamine;
- Shield DPA 15%, Registration Number 18983, containing a.i. diphenylamine; and
- Deccoquin 305 Registration Number 13544, containing a.i. ethoxyquin).

7.5.1.1 Non-chemical control practices

Low temperature or controlled atmosphere storage have been used to maintain fruit quality by delaying ripening. Apples can be stored in a refrigerated air facility at low temperatures of 0–3°C, with the storage temperature being cultivar specific, or apples can be stored under controlled atmosphere conditions. Controlled atmosphere storage facilities are airtight and are maintained at low temperatures of usually 0–3°C. They have an altered gaseous composition in which O_2 levels are typically 2.0–3.0% and CO_2 levels are 2.0–3.0% or 4.5–5.0%. Recommendations for temperature, O_2 and CO_2 are specific to cultivar and local conditions. Compared to low temperature air storage, controlled atmosphere storage is more effective in maintaining fruit firmness and acidity for longer storage periods, i.e., greater than 5–6 months. Fruit firmness and titratable acid retention may be further improved for some apple cultivars, such as McIntosh, Cortland, Spartan,

Golden Delicious and Red Delicious, by storing fruit under low O_2 controlled atmosphere regimens in which O_2 concentrations are reduced from the conventional 2.0–3.0% to 1.0–1.5%.

7.5.1.2 Chemical control practices

Chemical control practices include using the products mentioned in Section 7.5.1 to maintain fruit quality or reduce the incidence of storage scald. SmartFresh™ should not be tank mixed with any other products.

7.5.2 Compatibility with current management practices including integrated pest management

The purpose of this product is to control the undesirable side effects (ethylene production) of the natural maturation process that occurs when fruit are stored. SmartFresh™ is compatible with current management practices for maintaining apple quality while in storage. Storage in refrigerated air or controlled environments are the most widely used methods of keeping apples fresh. SmartFresh™ is compatible with both types of storage methods. Integrating SmartFresh™ as a postharvest, prestorage tool will further limit the maturation process.

7.5.3 Contribution to risk reduction

N/A

7.5.4 Information on the occurrence or possible occurrence of the development of resistance

SmartFresh™ is a plant growth regulator, that acts on the hormonal physiology of the fruit. Therefore, development of host resistance to the active ingredient is not an issue.

7.6 Conclusions

The submitted data support use of SmartFresh™ Technology on apples only. Treatment must be initiated within three days after harvest to apples that were cooled to 0–3°C within one day after harvest, or SmartFresh™ may be initiated within one day after harvest at temperatures of up to 23°C. Application is made in gas-tight, ambient temperature, refrigerated or controlled atmosphere food storage facilities of volumes ranging from 500 to 5400 m^3.

Efficacy data were sufficient to conditionally support the principal claim of maintaining fruit firmness for SmartFresh™ applied at the proposed maximum rate of 1.0 ppm 1-MCP. The following additional claims were supported:

- delay in rise of internal ethylene production and respiration;
- delay in ripening and senescence; and
- reduction of superficial scald.

Data supported a claim of superficial scald reduction for SmartFresh™ applied within 3 days after harvest; however, because the claim of fruit firmness maintenance is limited to SmartFresh™ applications made within 1 day after harvest at temperatures over 3°C, or to SmartFresh™ applications made within 3 days after harvest to fruit that was cooled to 0–3°C within 1 day after harvest, the claim of superficial scald reduction is limited to the 1 and 3 day application windows.

In support of an unconditional registration, additional efficacy data are required to support the proposed application rate of 1.0 ppm and to demonstrate that the proprietary device used in the application of the proposed formulation is effective in large room volumes.

7.6.1 Summary

A summary of accepted and unaccepted proposed use claims, based on the value assessment, is presented in Tables 7.6.1.1 to 7.6.1.4.

Table 7.6.1.1 Supported use claims—submitted data fully support use

Proposed claim	Supported claim
None	None

Table 7.6.1.2 Unaccepted use claims—absence of supporting data or provision of insufficient data

Proposed claim	Rationale for not supporting claim
Apply SmartFresh™ within two weeks of harvest	Limited data showed that application was effective for fruit firmness retention only when made immediately after harvest (within a day) where treatment took place at 13°C or when made at 0 or 3 days after harvest to fruit that were cooled to 3°C and treated at that temperature.
Application may be made in storage rooms and coolers	No data were provided.

Proposed claim	Rationale for not supporting claim
Maintaining titratable acidity	Insufficient data were provided.
Protection from external sources of ethylene	No data were provided.
Preventing soft scald on pome fruit	No data were provided.
Reducing incidence of peel greasiness in apples	Insufficient data were provided.
Reducing mealiness in pome fruit	No data were provided
Reducing chilling injury	No data were provided.

Table 7.6.1.3 Unaccepted use claims —irrelevance/unsuitability

Proposed claim	Rationale for not supporting claim
Application may be made in enclosed truck trailers, shipping containers or greenhouses	Truck trailers are of a volume of less than 500 cubic metres. Greenhouses are not airtight and fruit may be subjected to excessive heat. Treatment within one day would preclude treatment in a shipping container.

Table 7.6.1.4 Supportable use claims—further data or information must be provided

Proposed claim	Supported claim
The label claims below are conditional upon submission and review of operational trial data and data to support the need for the proposed rate of 1.0 ppm	
Host crop	
Pome fruit	Supported for apples (data were provided for apples only).

Proposed claim	Supported claim
The label claims below are conditional upon submission and review of operational trial data and data to support the need for the proposed rate of 1.0 ppm	
Use directions	
Application rate: maximum 1.0 ppm (average of 0.875 ppm) with exact concentration a function of room volume and soluble packet size.	Supported. Data are required from studies in which firmness of fruit treated with the proposed rate of 1-MCP is compared to the rate of 0.625 ppm registered in the UK over a period of up to and including 11 months.
Application timing: within two weeks after harvest	Data support an application window of three days for apples that were cooled to 0–3°C within one day after harvest, or an application window of one day after harvest at treatment temperatures of up to 23°C.
Application equipment: Use of a proprietary device to apply the proposed SmartFresh™ formulation (3.3% 1-MCP) in commercial refrigerated air or controlled atmosphere storage facilities.	Supported. No data were submitted from studies in which 1-MCP was applied to apples in commercial-scale storage facilities using the proposed SmartFresh™ formulation and application device, and stored for up to 11 months.
Application sites: ambient temperature, refrigerated or controlled atmosphere food storage facilities.	Supportable. Data are required for airtight refrigerated and controlled atmosphere food storage facilities with a volume of at least 500 cubic metres.
Application temperature: under cool (13°C) and warm (above 13°C) conditions	Data support an application temperature of 0–23°C.
Application duration: 24 hours	Supported.
Number of applications per year: one, with the possibility of a repeat application just before sale	Supported for one application per year to any one lot of apples.

Proposed claim	Supported claim
The label claims below are conditional upon submission and review of operational trial data and data to support the need for the proposed rate of 1.0 ppm	
Application to fruit to be stored in refrigerated air or controlled atmosphere facilities	Supported for fruit stored in refrigerated air facilities for up to 6 months or controlled atmosphere facilities for 9 months.
Efficacy claims	
Maintaining fruit firmness	Supported.
The following claims are conditional upon principal claim of maintenance of fruit firmness being supportable for unconditional registration.	
Reduction in internal ethylene production	A claim of delay in rise of internal ethylene production is supported.
Reduction in respiration	A claim of delay in rise of respiration is supported.
Delay in ripening and senescence	Supported.
Preventing superficial scald on pome fruit	A claim of reduction in superficial scald is supported.

8.0 Toxic Substances Management Policy

During the review of 1-MCP and the end-use product SmartFresh™ Technology, the PMRA has taken into account the federal TSMP[1] and has followed its Regulatory Directive DIR99-03[2]. It has been determined that this product does not meet TSMP Track 1 criteria for the following reasons:

- 1-MCP does not meet the criteria for persistence in water, air and sediment. Due to its high volatility, 1-MCP is not expected to persist in water, on soil or in water/sediment systems. Its values for half-life in water and sediment in whole water/sediment systems are expected to be below the TSMP Track 1

[1] The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics

[2] Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our website at www.pmra-arla.gc.ca

cut-off criteria for water (> 182 days), soil (>182 days) and sediment (>365 days). 1-MCP degrades quickly in the atmosphere via reactions with ozone and hydroxyl radicals.

- 1-MCP is not expected to be bioaccumulative based on its chemical structure.
- The toxicity of 1-MCP is described in Section 3.1.
- 1-MCP does not contain any by-products or microcontaminants that are TSMP Track 1 substances as identified in Appendix II of DIR99-03. Impurities of toxicological concern identified in Section 2.13.4 of DIR98-04 and TSMP Track 1 substances are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

The formulated product does not contain any formulants that are known to contain TSMP Track 1 substances.

9.0 Regulatory decision

9.1 Regulatory decision

The active ingredient 1-methylcyclopropene (1-MCP) and its associated EP, SmartFresh™ Technology, have been granted temporary registrations for posthavest use on apples, pursuant to Section 17 of the Pest Control Products Regulations, subject to the following conditions:

- submission of efficacy data to demonstrate the lowest effective rate of application; and
- submission of efficacy data from operational trials to demonstrate that the proprietary device used in the application of the proposed formulation is effective in enclosed rooms of up to 5400 m^3.

9.2 Additional data requirements

DACO 10.2.3.3 Efficacy: Small-scale trials (Field, Greenhouse)

Data are required from trials in which the efficacy of SmartFresh™ Technology applied at the proposed rate of 1.0 ppm 1-MCP is compared to the 1-MCP rate of 0.625 ppm registered in the UK. Both application concentrations must be evaluated for fruit stored in a refrigerated air facility and for fruit stored in a controlled atmosphere facility. Fruit of early, mid-season and late maturing cultivars should be tested, and include the McIntosh cultivar. Evaluations of fruit firmness are to be made at up to and including six months after treatment for refrigerated air storage, and at up to and including 11 months after treatment for controlled atmosphere storage.

DACO 10.2.3.4 Efficacy: Operational trials

Data are required from operational trials in which the proprietary application device is used to deliver 1-MCP from SmartFresh™ Technology at the recommended concentration in storage rooms of varying sizes. Evaluations of fruit firmness are to be made at up to and including six months after treatment for refrigerated air storage, and at up to and including 11 months after treatment for controlled atmosphere storage. Efficacy of the product applied in a large room must be demonstrated.

List of abbreviations

1-MCP	1-methylcyclopropene
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CMP	3-chloro-2-methylpropene
CO_2	carbon dioxide
DACO	data code
DPA	diphenylamine
FID	flame ionized detection
FOB	functional observation battery
g	gram(s)
GC	gas chromatography
HAFT	highest average field trial
HCT	hematocrit
HGPRT	hypoxanthine-guanine phosphoribosyltransferase
HGT	hemoglobin
hr	hour(s)
ILV	independent laboratory validation
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOQ	limit of quantitation
LSC	liquid scintillation counting
MAS	maximum average score
mCi	millicurie
mg	milligram(s)
MIS	maximum irritation score
mL	millilitre
MOE	margin of exposure
nm	nanometres
NOAEL	no observed adverse effect level
NZW	New Zealand white
OH	hydroxyl radicals
O_2	oxygen
Pa	Pascal(s)
PDI	potential daily intake
ppb	parts per billion
ppm	parts per million
QA/QC	quality assurance/quality control
RBC	red blood cell
SDEV	standard deviation
STMdR	supervised trial median residue

TGAI	technical grade active ingredient
TRR	total radioactive residue
v/v	volume per volume
w/w	weight per weight
µg	microgram(s)
µL	microlitre(s)

Appendix I Toxicology

METABOLISM: The fate of 1-methylcyclopropene was investigated in male and female rats (Sprague Dawley) after single inhalation administration of ^{14}C labelled compound at dose levels of 100 ppm (0.22 mg/L) and 1000 ppm (2.21 mg/L)(two-high dose groups).

Absorption: Rapid but limited.

Distribution: Twenty-four hours after administration, the highest residues were predominantly found in the lung, liver, kidney spleen and fat respectively in both males and females. Less than 1.8% of the administered dose remained in the tissues at sacrifice in both males and females at all doses. Whole blood and plasma levels peaked at the end of exposure and decreased until the time of study termination.

Excretion: The absorbed radioactivity was rapidly excreted. The route and rate of excretion were independent of the sex or dose level. Within 24 hours of dosing, less than 5% of the administered dose was excreted, mainly via urine. The majority of the test substance was exhaled.

Metabolism: The limited availability and the levels of the ^{14}C-1-methylcyclopropene used and recovered were too low to identify and/or quantify the metabolites and, therefore, no metabolic pathway was established. The majority of the test substance was inhaled and exhaled without being metabolized.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES—TECHNICAL			
Oral	Waiver		
Dermal	Waiver		
Inhalation	Crl:CD®BR rat 5/sex/dose **Dose level:** 2.5 mg/L	Male and Female LC_{50} > 2.5 mg/L	No mortalities, no clinical signs. **Low Toxicity**
Skin irritation	Waiver		
Eye irritation	Waiver		
Skin sensitization (Test method)	Waiver		
ACUTE STUDIES—FORMULATION [1-Methylcyclopropene Alpha-Cyclodextrin Complex]			
Oral	Crl:CD®BR rat 5/sex/dose **Dose level:** 5000 mg/kg bw/day	Male and Female LD_{50} > 5000 mg/kg bw/day	• scant faeces days 1 and 2 (males, females) **Low toxicity**
Dermal	Crl:CD®BR rat 5/sex/dose **Dose level:** 5000 mg/kg bw/day	Male and Female LD_{50} > 5000 mg/kg bw/day	• erythema, pocketing edema, edema dark areas, dessication and scabs in days 1 through 14 (males, females) • deceased body weight gain (24%) in males **Low toxicity**
Inhalation	Waiver		
Skin irritation	NZW rabbits 6 males **Dose level:** 0.1 g	Males MAS = 0.33/8 (24, 48 and 72 hours) MIS = 0.5/8 (1 hour)	• erythema in two test animals starting at 1 hour in one case, 24 hours in the other, and persisting to 72 hours in both cases **Minimally irritating**

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Eye irritation	NZW rabbits 6 males **Dose level:** 0.5 g	Males MAS = 0.56/110 (24, 48 and 72 hours) MIS = 5/110 (1 hour)	• conjunctival redness that subsided within 72 hours • conjunctival swelling that subsided within 24 hours • conjunctival discharge that subsided within 24 hours **Minimally irritating**
Skin sensitization (maximization)	Hartley guinea pigs 20 females **Dose levels:** • 10% (w/w) mixture in mineral oil for intradermal injection • 0.4 g moistened with mineral oil for topical	• hexyl-cinnamaldehyde positive control Test material did not give a positive skin sensitization response	**Not a dermal sensitizer**
SHORT-TERM TOXICITY			
Short-term oral (90 day) (rodent)	Waiver		
Short-term oral (6–12 month) (non-rodent)	Waiver		
Short-term dermal (21 day, 30 day)	Waiver		
Short-term inhalation range-finding (females) 2 weeks	Crl:CD®BR Rat 7 females/dose level **Dose levels**: 0.0 mg/L (0 mg/kg bw/day) 0.23 mg/L (45 mg/kg bw/day) 0.67 mg/L (95 mg/kg bw/day) 2.21 mg/L (312 mg/kg bw/day)		**<u>95 and 312 mg/kg bw/d</u>** • extramedullary hematopoeisis in spleen **<u>312 mg/kg bw/d</u>** • ↓RBCs, HGB, HCT • ↑ bilirubin • ↑ absolute and relative spleen weight • ↑ discolouration and enlargement of spleen • ↓ body weight
Short-term inhalation range-finding (males) 2 weeks	Crl:CD®BR Rat 4 males/dose level **Dose levels**: 0.0 mg/L (0 mg/kg bw/day) 0.05 mg/L (9 mg/kg bw/day) 0.23 mg/L (45 mg/kg bw/day) 2.29 mg/L (448 mg/kg bw/day)		**<u>448 mg/kg bw/d</u>** • ↓ RBCs, HCT and HGB • ↑ relative and absolute spleen weight • ↑ hyaline droplets in the kidneys

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Short-term inhalation 90-day	Crl:CD®BR Rat 10/sex/dose **Dose levels**: 0.0 mg/L (0 mg/kg bw/day) 0.05 mg/L (9 mg/kg bw/day) 0.24 mg/L (45 mg/kg bw/day) 2.27 mg/L (444 mg/kg bw/day)	NOAEL 9 mg/kg bw/day LOAEL 45 mg/kg bw/day	**45 and 444 mg/kg bw/d** • intracytoplasmic eosinophilic structures consistent with hyaline droplets in the epithelium cortical tubules (males) • hemosiderin primarily in red pulp of spleen (males, females) **444 mg/kg bw/d** • extramedullary hematopoesis in spleen (males, females) • ↑ relative liver weight (males, females) • ↑ absolute liver weight (females) • ↑ absolute and relative spleen weight (males, females) • ↑ absolute kidney weights (females) • enlarged spleen (males, females) • ↓ RBCs, HCT and HGB (males, females)
CHRONIC TOXICITY AND ONCOGENICITY			
Chronic 78-week dietary 2-year dietary	Waivers		
REPRODUCTION AND DEVELOPMENTAL TOXICITY			
Multi-generation	Waiver		
Developmental toxicity (rodent)	Crl:CD®BR Rat 22 females/dose level **Dose Levels**: 0.0 mg/L (0 mg/kg bw/day) 0.23 mg/L (45 mg/kg bw/day) 0.73 mg/L (142 mg/kg bw/day) 2.25 mg/L (440 mg/kg bw/day)	**Maternal** NOAEL 45 mg/kg bw/day LOAEL 142 mg/kg bw/day **Fetal** NOAEL 440 mg/kg bw/day	**Maternal** **142 and 440 mg/kg bw/d** • darked spleens • enlarged spleens **440 mg/kg bw/d** • ↓ body weight gain over treatment period (G6 to G20, particularly between G6 and G9) • ↓ food consumption G6 to G9 **Fetal** • no treatment-related findings
Developmental toxicity (non-rodent)	Waiver		
GENOTOXICITY			
STUDY	**SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES**		**RESULTS**
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 102, TA 1535 and TA 1537 0, 0.22×10^3, 0.66×10^3 and 2.21×10^3 µg/plate; with and without activation		negative
Gene mutations in mammalian cells in vitro	Chinese hamster ovary cells (HGPRT locus) 0, 0.22×10^3, 0.55×10^3, 1.10×10^3 and 2.21×10^3 µg/mL; with and without activation		negative

STUDY	SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES	RESULTS
Chromosome aberrations in vitro	Chinese hamster ovary cells 0, 0.22×10^3, 0.66×10^3 and 2.21×10^3 µg/mL; with and without activation	negative
Micronucleus assay (in vivo)	Male and female CD®BR rats 0, 43, 130 or 433 mg/kg (single 6-hour inhalation dose; bone marrow harvested 22, 48 and 72 hours post-dosing)	negative
Recommended ARfD: An ARfD was not set since there is no acute hazard.		
Recommended ADI: An ADI was not set due to a lack of data. **MOE for other critical endpoint(s):** 800 000		

Appendix II Residues

Table 1 Integrated food residue chemistry summary

DIRECTIONS FOR THE POSTHARVEST TREATMENT USE OF 1-MCP			
Crop	**Function**	**Proposed Rate**	
		g a.i./1000 m^3	**ppm (v/v)**
Apple	Plant growth regulator—ethylene receptor antagonist on plant cell membrane	1.5–2.3	1

PHYSICOCHEMICAL PROPERTIES	
Melting point/range	N/A (The product is a dust at room temperature)
pH	N/A
Density	2.24 g/L (calculated) at 20°C
Water solubility (20°C)	137 mg/L, no pH effect
Solvent solubility	Solvent — Solubility (g/L) heptane — 2.5 xylene — 2.3 ethyl acetate — 12.5 methanol — 11.25 acetone — 2.4 dichloromethane — 2.0
Vapour pressure at 25°C	2×10^5 Pa (calculated)
Dissociation constant (pK_a)	N/A (The product contains no acid or base functionality)
n-octanol–water partition coefficient log (K_{ow})	log K_{ow} = 2.4 (no pH effect)
UV-visible absorption spectrum	No absorbance maxima observed above 205 nm.

ANALYTICAL METHODOLOGY	
Parameters	**Plant matrices (Apple)**
Method ID	Report No. AF-01-173
Type	Enforcement
Analyte	1-methylcyclopropene (1-MCP)
Instrumentation	Gas chromatograph equipped with flame ionization detector (GC/FID)
LOQ	0.01 ppm
Standard	External standard using isobutene as surrogate calibration standard
ILV	Acceptable validation of the GC/FID method (Report No. AF-01-173) was completed using apples.
Extraction	Apples are homogenized with basic (pH 11) saturated ammonium sulfate solution in an air tight preparation unit. The released 1-MCP is trapped in the head space of the preparation unit. The head space is sampled directly for analysis.
Radiovalidation	Not required
Multiresidue method	Not possible given the nature of 1-MCP

NATURE OF THE RESIDUE IN PLANTS	
Crop	**Apple**
Radiolabel	^{14}C-1-methylcyclopropene
Test Site	Sealed treatment chamber made of aluminum and having a volume of 99 litres maintained at 0–3ºC or ambient (19.4–25.6°C) temperatures
Treatment	Postharvest
Pre-treatment handling	Mature apples were stored (0–3°C) for 13 days to 17 months from the time of harvest until treatment
Rate	1.2 ppm (v/v) for 24 hours or 7 days
No. of treatments	1
EP	SmartFresh™ Technology (containing 3.3% w/w 1-MCP encapsulated in α-cyclodextrin)
Post-treatment interval	At the end of treatment, the chamber was vented with air for 15–30 min. Apple samples were collected from the chamber 0–336 hrs after venting.
Characterization/Identification	As TRRs in whole apple, determined by summing ^{14}C-residues in head space, filtrate and filter cake, did not exceed 0.01 ppm, further identification/characterization was not carried out.
Residue of concern	The parent only, 1-MCP
CONFINED AND FIELD ACCUMULATION IN ROTATIONAL CROP STUDIES	
SmartFresh™ Technology (containing 1-MCP) is a product intended for postharvest use on stored apples to delay the production of ethylene (ripening process). Therefore, based on the use pattern, confined and field accumulation in rotational crop studies were not required.	
NATURE OF THE RESIDUE IN LIVESTOCK	
When treated at 1.2 ppm (v/v) for 24 hours or 7 days and vented 15–30 minutes following treatment, total residues of 1-MCP in apples stored at 0–3°C or ambient (19.4–25.6°C) temperature did not exceed 0.01 ppm. Accordingly, when treated apples are processed into apple pomace (potential feed), residues of 1-MCP are not expected to concentrate. Therefore, exposure to treated apple pomace is not likely to result in a measurable transfer of 1-MCP residues to meat and milk. As such, a ruminant metabolism study was not required. Apple pomace is not a recognized poultry feed item. Therefore, a poultry metabolism study was not required.	
STORAGE STABILITY	
Given the reactivity and instability of 1-MCP, treated apple samples were analysed the day of sampling. Therefore, freezer storage stability studies were not required.	

CROP FIELD TRIALS—APPLE AS POSTHARVEST TREATMENT

Eight trials were conducted on four varieties of apples (Red Delicious, Gala, Granny Smith and Fuji) stored in a treatment chamber maintained at temperature settings of 0–3°C or 19.4–25.6°C (ambient). Apples were treated with ^{14}C-1-MCP at 1.2 ppm (v/v) for 24 hours after which the chamber was vented for 15-30 minutes with air at a flow rate of 40L/minute. An additional trial was conducted in which apples were stored at 0–3°C, treated for 7 days and sampled 0–48 hrs after venting.

Commodity	Duration of treatment	Storage temperature (°C)	Post-venting interval (hours)	Residue levels (ppm)				
				Min.	Max.	HAFT	Median (STMdR)	SDEV
Apple	24 hours	0–3	0–336	0.001	0.006	0.005	0.0035	0.001
	24 hours	19.4–25.6	0–192	0.002	0.009	0.007	0.0039	0.002
	7 days	0–3	0–48	0.007	0.008	0.007	0.0067	0

MAXIMUM RESIDUE LIMITS

Apple	0.01 ppm

PROCESSED FOOD AND FEED

Maximum residues of 1-MCP in apples stored at 0–25.6°C, treated at 1.2 ppm (v/v) for up to 7 days and sampled 0–336 hours following venting were 0.009 ppm. Processing of treated apples into various commodities including juice and sauce is not expected to result in a concentration of 1-MCP residues. Therefore, based on the findings of the apple residue data, a processing study was not required.

LIVESTOCK FEEDING

The residue data demonstrated that when apples were stored at 0–25.6°C, treated at 1.2 ppm (v/v) for up to 7 days and sampled at various intervals following venting, total residues of 1-MCP ranged from 0.001–0.009 ppm. When treated apples are processed into feed (apple pomace), residues are not expected to exceed 0.01 ppm. Therefore, transfer of measurable residues of 1-MCP into meat and milk following exposure to treated apple pomace is not anticipated. As such, a dairy cattle feeding study was not required.

Table 2 Overview of plant/animal metabolism studies and risk assessment

PLANT STUDIES	
CROPS (N=1)	**1-methylcyclopropene (1-MCP)**
	apple
ROC FOR MONITORING AND MAXIMUM RESIDUE LIMIT	Parent only (1-MCP)
ROC FOR RISK ASSESSMENT	Parent only (1-MCP)
METABOLIC PROFILE IN DIVERSE CROPS	1-MCP appears to readily breakdown and subsequently become incorporated into natural plant constituents
ANIMAL STUDIES	
Animal studies were not required as there is no expectation that residues of 1-MCP in treated apples, processed into apple pomace and fed to livestock, will result in a measurable transfer of residues into meat and milk.	
DIETARY RISK FROM FOOD	
The proposed domestic use of SmartFresh™ Technology (containing 3.3% w/w 1-MCP) as a postharvest treatment to stored mature apples does not pose an unacceptable dietary risk to any segment of the population, including infants, children, adults and seniors. As well, there is negligible concern regarding the 3-chloro-2-methylpropene (CMP) impurity, as the level in the EP is very low (0.000561%).	

Appendix III Environmental assessment

Table 1 Fate and behaviour in the terrestrial and aquatic environment

Property	Test substance	Value (half-life)	Comments
Terrestrial			
Abiotic transformation			
Hydrolysis at (50°C)	1-MCP	Not available	Not an important route of transformation based on vapour pressure and Henry's law constant
Laser photolysis (OH reaction)	1-MCP	4.4 hours	Estimated important route of transformation
Photo-oxidation (Atkinson model)	1-MCP	0.123 to 0.65 hours (at 12 and 24 hours of OH) 0.65 hours (with ozone concentration of 1×10^{11} molecules/cm^3)	Estimated important route of transformation
Aquatic			
Hydrolysis at (50°C)	1-MCP	Not available	Not an important route of transformation based on vapour pressure and Henry's law constant