Proposed Regulatory Decision Document PRDD2001-04

Ethylene
Eco Sprout Guard

The active ingredient ethylene, as Eco Sprout Guard technical grade active ingredient (TGAI) and the associated end-use product Eco Sprout Guard EP containing 2–100% ethylene in compressed gas cylinders for the control of sprouting in stored "Russet Burbank" processing potatoes, are proposed for registration under Section 13 of the Pest Control Products Regulations.

This proposed regulatory decision document (PRDD) provides a summary of data reviewed and the rationale for the proposed full registration of these products. The Pest Management Regulatory Agency (PMRA) will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address listed below.

(publié aussi en français) **October 5, 2001**

This document is published by the Submission Coordination and Documentation Division, Pest Management Regulatory Agency. For further information, please contact:

Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6602A
Ottawa, Ontario
K1A 0K9

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

ISBN: 0-662-31130-2
Catalogue number: H113-9/2001-4E-IN

Foreword

The submissions for registration of Eco Sprout Guard TGAI (ethylene) and its end-use product Eco Sprout Guard EP, supplied by Praxair Inc. and marketed by McCain Foods Limited, have been reviewed by the Pest Management Regulatory Agency (PMRA).

Eco Sprout Guard EP, containing 2–100% ethylene in compressed gas cylinders, was investigated as an alternative product to conventional pesticides for the inhibition of sprouting in stored processing potato tubers. Ethylene occurs ubiquitously in the natural environment and is a natural plant hormone. Ethylene is relatively nontoxic and has a long history of use as a clinical anaesthetic at high concentrations (up to 80–90% in oxygen). At the recommended concentration of 4 ppm, ethylene inhibits excessive sprout growth by reducing apical dominance. Levels of ethylene and its major metabolites in treated potatoes are similar to those in untreated potatoes.

The PMRA has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient, pursuant to Section 18.b, to allow a determination of the safety, merit and value of *Eco Sprout Guard TGAI (ethylene) and its end-use product Eco Sprout Guard EP*. The Agency has concluded that the use of *Eco Sprout Guard TGAI (ethylene) and its end-use product Eco Sprout Guard EP* in accordance with the label has merit and value consistent with section 18.c of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18.d. Therefore, based on the considerations outlined above, the use of *Eco Sprout Guard TGAI (ethylene) and its end-use product Eco Sprout Guard EP* is proposed for full registration, pursuant to Section 13 of the Pest Control Products Regulations.

The PMRA is proposing to grant full registration to this product. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed registration decision for this product.

Table of Contents

1.0 The active substance, its properties, and uses

1.1 Identity of the active substance and preparation containing it

Active substance	Ethylene
Function	Sprout inhibitor
Chemical name	
1. International Union of Pure and Applied Chemistry	Ethene
2. Chemical Abstract Services (CAS)	Ethene
CAS Number	74-85-1
Molecular formula	C_2H_4
Molecular weight	28.06
Structural formula	$CH_2{=}CH_2$
Nominal purity of active	Pure ethylene gas, 100%
Identity of relevant impurities of toxicological, environmental, and other significance	The product contains carbon monoxide at a maximum level of <0.1%. Impurities of toxicological concern as identified in Section 2.13.4 of DIR98-04 *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* or Toxic Substances Management Policy (TSMP) Track-1 materials as identified in Appendix II of DIR99-03 *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy* are not expected to be present or formed in the product.

1.2 Physical and chemical properties of the active substance and end-use product

Technical product: Eco Sprout Guard TGAI

Property	Result	Comment
Colour and physical state	Colourless compressed gas	
Odour	Sweet odour	
Melting point/range	N/A	
Boiling point/range	–103EC	
Specific gravity	0.978 at 0EC (air = 1)	
Vapour density (g/mL)	0.001 26 at 0EC	
Ultraviolet (UV) / visible spectrum	Not expected to absorb UV at wavelengths >300 nm	Photolysis will not be expected
Solubility in water at 20EC	Slightly	
n-Octanol/water partition coefficient (K_{ow})	log K_{ow} = 1.16	Bioaccumulation is not expected
Dissociation constant	Does not dissociate	
Stability (temperature, metal)	The flash point is –136EC. Avoid impact and high temperature at cylinder pressure; incompatible with oxidizing agents, halogens, acid, aluminum chloride and halocarbons	

End-use product: Eco Sprout Guard EP

Property	Result
Colour	Colourless
Odour	Sweet

Property	Result
Physical state	Gas
Formulation type	Compressed gas
Guarantee	2–100%, nominal
Formulants	The product does not contain any EPA List 1 formulants or formulants known to be TSMP Track-1 substances.
Container material and description	Compressed gas cylinders
Oxidizing or reducing action	Incompatible with oxidizing agents, halogens, acids, aluminum chloride and halocarbons
Storage stability	Expected to be stable when stored in the cylinders
Explodability	Spontaneously explosive in sunlight with chlorine. Forms explosive mixture with air and oxidizing agents. Containers may rupture due to heat or fire. Avoid impacts against containers.

1.3 Details of uses

Ethylene is a growth regulator. In potato tubers, ethylene has been documented to shorten the post-harvest rest period, often resulting in earlier sprouting but inhibiting the elongation of sprouts by reducing apical dominance.

Eco Sprout Guard EP, containing from 2 to 100% ethylene in pressurized cylinders, is recommended for application to “Russet Burbank” processing potato tubers in commercial potato storages. Eco Sprout Guard EP is recommended for daily application into the ventilation airstream of the storage facility to attain an ethylene concentration of up to 4 ppm.

2.0 Methods of analysis

2.1 Methods for analysis of the active substance as manufactured

The active was determined using two gas chromatographic (GC) methods.

2.2 Method for formulation analysis

The active was determined using two GC methods.

3.0 Impact on human and animal health

3.1 Integrated toxicological summary

Ethylene is a naturally occurring gaseous chemical produced by all plant tissues in significant amounts and acts as an endogenous plant growth regulator. Ethylene is also a naturally occurring endogenous chemical in humans and laboratory animals and has been identified in the air exhaled by unexposed rats and humans. Possible sources of endogenous ethylene in humans and laboratory animals include lipid peroxidation of unsaturated fats, oxidation of free methionine, oxidation of hemin in haemoglobin and metabolism of intestinal bacteria. In humans, the concentration of ethylene in the blood resulting from its endogenous production is approximately 0.097 nmol/L.

Under environmental conditions, ethylene is a gas; therefore, the most probable route of human exposure to ethylene is by inhalation. Ethylene at high concentrations (up to 80–90% in oxygen) has a long history of use as a clinical anaesthetic, with little concomitant toxicity. Anaesthesia is complete within 20–30 min with 90% in oxygen. Ethylene is more advantageous than ether as an anaesthetic because of safer induction and more rapid recovery. Ethylene has been classified as an asphyxiant in Canada because its presence at high concentrations in air lowers the available oxygen concentration.

The uptake, exhalation and metabolism of ethylene can be described by first-order kinetics. Uptake of ethylene into the body is low due to its low solubility in blood. For rats it is estimated that approximately 15–17% of inhaled ethylene reaches the alveolar blood. In humans, it is estimated that approximately 21% of inhaled ethylene reaches the alveolar blood using a physiological toxicokinetic model which is similar to values obtained for rats. Inhalation of ethylene in human volunteers at atomospheric concentrations of up to 50 ppm by gas uptake in a closed spirometer system indicates that at an alveolar ventilation rate of 150 L/h, approximately 5.6% of inhaled ethylene reaches the alveolar blood with the majority, 94.4%, being exhaled again without becoming systemically available via the blood system. At steady state the estimated alveolar retention in humans is approximately 2–3%. Due to its low blood/gas solubility, ethylene is rapidly excreted and does not appear to accumulate in the body. Ethylene from both endogenous and exogenous sources is metabolized to ethylene oxide in vivo in rats, mice and humans. Studies in healthy volunteers suggest that approximately 2–3% of ethylene absorbed is metabolized to ethylene oxide, whereas up to 98% of ethylene is exhaled unchanged. The data also suggest that the metabolism of ethylene can be stimulated by an inducer of the mixed-function oxidase system.

Ethylene has low acute toxicity via the inhalation route of exposure in mice. There is some acute hazard of dermal and ocular frost burns and of flammability posed by the compressed gas. In a subchronic inhalation study with Sprague-Dawley rats, there were no toxic effects at concentrations up to and including 10 000 ppm, the highest dose tested. In a chronic toxicity/oncogenicity inhalation study with Fischer 344 rats, no significant treatment-related findings or evidence of oncogenicity were observed at ethylene concentrations up to and including 3000 ppm, the highest dose tested. The weight of evidence suggests that ethylene is not genotoxic. There is inadequate evidence in humans and experimental animals for carcinogenicity of ethylene. Overall, ethylene is not classifiable as to its carcinogenicity to humans (International Agency for Research on Cancer (IARC) classification - Group 3). Ethylene is not listed as a carcinogen by the National Toxicology Program (NTP) or Occupational Safety and Health Association (OSHA).

The toxicological concerns regarding ethylene are related primarily to its metabolites, specifically the initial metabolite, ethylene oxide. Ethylene oxide is a direct alkylating agent that is genotoxic in numerous in vitro and in vivo test systems and is carcinogenic in mice and rats. Positive results have been obtained using the mouse lung tumour bioassay ($\geq$70 ppm) and the standard 2-year bioassays in mice and rats at concentrations $\geq$100 ppm. Based on these findings, ethylene oxide is classified as carcinogenic to humans by IARC (IARC classification - Group 1) and NTP (*Report on Carcinogens*, 9th edition “known carcinogen”). However, published literature indicates that exposures to 1000 and 40 ppm ethylene in closed inhalation chambers are equivalent to ethylene oxide exposures of 5.6 and 1 ppm, respectively, in rats. When exposure data was combined with previously obtained rat tumour induction data for ethylene oxide, extrapolation of the tumour data to the highest possible ethylene oxide equivalent, 5.6 ppm, indicated that high ethylene exposures would not result in tumour incidence more than 2% above the tumour background level. It was concluded that the body burden of ethylene oxide resulting from such low ethylene oxide exposures (i.e., 5.6 ppm) is too small to lead to a significant increase in tumours in ethylene exposed rats. Published literature also indicates that above concentrations of approximately 1000 ppm ethylene, the V_{max} for ethylene is reached, thus, higher exposures would not yield greater conversion of ethylene to ethylene oxide. Published literature suggest that it would be difficult to obtain statistically significant positive tumour results for ethylene regardless of the dose. In humans, using a physiological model, predicted blood levels resulting from one 8-h exposure to 1 ppm ethylene oxide would be equivalent ethylene oxide levels expected following an 8-h exposure to 45 ppm ethylene assuming bioavailability of 100% for the metabolically formed ethylene oxide (there is some evidence that at low ethylene exposure concentrations the bioavailability of metabolically formed ethylene oxide may be 100%). Based on measurements of haemoglobin adduct levels in humans exposed to up to 5 ppm ethylene, it is estimated that an average of 2–3% of absorbed ethylene is metabolized to ethylene oxide. The current threshold for ethylene oxide of 1 ppm [current OSHA standard for ethylene oxide, i.e., 8-h time-weighted average (TWA) per 40-h work week] is toxicologically equivalent to an ethylene concentration of 37 ppm. Published literature indicates that long-term human occupational exposure to low airborne concentration of ethylene oxide, at or below current occupational exposure limits of 1 ppm (1.83 mg/m^3) would not produce unacceptable increased genotoxic or carcinogenic risk.

Based on these findings and on the proposed conditions of use for ethylene (the ethylene concentration will be a maximum of 4 ppm until the end of the storage period), it is unlikely that ethylene oxide concentrations would reach levels that would produce unacceptable genotoxic or carcinogenic risks.

There is sufficient information from published literature to make a risk assessment for the proposed use of ethylene. Based on information from published literature, ethylene has low toxicity concerns and has been used extensively as an anaesthetic with little concomitant toxicity. Based on the proposed low levels of ethylene exposure, the low absorption rate for ethylene and the low conversion rate of ethylene to ethylene oxide, it is unlikely that ethylene oxide levels would reach unacceptable levels (i.e., >1.0 ppm). It can be concluded that ethylene will be nontoxic to humans under the conditions of use as a plant growth regulator for suppression of sprout growth on stored potatoes, provided that it is used as indicated on the product label; therefore, under the proposed conditions of use as indicated on the product label, it is unlikely that ethylene will present a risk.

3.2 Determination of acceptable daily intake

As indicated by the Health Protection Branch of Health Canada in the "Health and Safety Status Report" for ethylene (May 1994), an acceptable daily intake (ADI) is not required for ethylene, since it is a naturally occurring chemical produced by fruits and vegetables, including potatoes, during senescence. Ethylene is also a naturally occurring endogenous chemical in humans and laboratory animals and has been identified in the air exhaled by unexposed rats and humans. Potential ethylene metabolites have also been shown to occur naturally. Analytical data for these metabolites in treated potatoes showed that residue levels were either nondetectable or were at levels similar to any measurable residues found in controls.

3.3 Acute reference dose

An acute reference dose (ARfD) was not established, since ethylene was considered unlikely to present an acute hazard. The available literature suggests that there are no significant treatment-related findings to indicate a concern in acute dietary risk assessment. The potential risks to humans from exposure to ethylene are considered negligible due to low toxicity concerns and the widespread use of ethylene as an anaesthetic with little concomitant toxicity.

3.4 Toxicology end-point selection—occupational and bystander risk assessment

The primary route of exposure is inhalation. Ethylene has low acute toxicity via the inhalation route. Ethylene is considered a simple asphyxiant. In a subchronic inhalation study from the published literature, there were no toxic effects in Sprague-Dawley rats at concentrations up to and including 10 000 ppm, the highest dose tested. In a published chronic toxicity/oncogenicity inhalation study with Fischer 344 rats, no significant treatment-related findings or evidence of oncogenicity were observed at ethylene concentrations up to and including 3000 ppm, the highest dose tested. Contact with ethylene as a compressed gas can cause dermal and ocular frost burns and present a hazard due to its flammability. Potential for this type of exposure can be mitigated through labelling. This was considered to be the most appropriate regulatory approach for this active ingredient and a qualitative assessment of exposure and risk for the proposed use of ethylene was conducted.

3.5 Impact on human and animal health arising from exposure to the active substance or to its impurities

3.5.1 Operator exposure assessment

Application to stored potatoes

Eco Sprout Guard consists of compressed ethylene gas contained in pressurized cylinders of varying concentrations (ranging from 2 to 100% ethylene), the balance being made up with nitrogen. Eco Sprout Guard would be applied by releasing the gas in the ventilation system of the potato storage facility at a specific rate up 4 ppm for the duration of the storage period. The proposed label indicates that for best results application must begin at 1–7 days after the potatoes are harvested and continue until 1–7 days before processing. Typically storage operators would have gas cylinders containing concentrations of ethylene to be used. The concentration in the storage facility would be determined by the delivery rate and the percent concentration of ethylene in Eco Sprout Guard. The concentration of ethylene in the storage building would be monitored, continuously and remotely, to ensure that it remains near the target level throughout the storage period. Typically, the ethylene gas delivery system uses programmable controls to operate valves in response to ventilation conditions in the building. The system is self contained and requires human intervention to review and adjust parameters, to connect or disconnect cylinders to replace empty ones or in the event of a leak in the system.

Operator exposure

Potential occupational exposure to ethylene may occur when entering the storage building or its ventilation duct work (e.g., for repair) during application of ethylene or when standing near the ventilation exhaust. The primary route of exposure would be inhalation.

Ethylene is a naturally occurring gaseous chemical produced by both plants and animals. It has had a long history of use as a clinical anaesthetic (anaesthesia is obtained with exposure to concentrations of 80–90% in oxygen) with little concomitant toxicity. It is generally recognized as safe (GRAS) in the U.S. No exposure limits have been established for ethylene by the American Conference of Governmental Industrial Hygienists (ACGIH). The ACGIH classifies ethylene as a “simple asphyxiant.” Respiratory protection is not normally required for simple asphyxiants except in emergency or planned entry into unknown concentration or in areas of oxygen deficiency. In a published subchronic inhalation study with Sprague-Dawley rats, there were no toxic effects at concentrations up to and including 10 000 ppm, the highest dose tested. A 2-year chronic rat inhalation study from the published literature showed no effects in rats exposed to 3000 ppm ethylene (6 h/day, 5 days/week). Based on this, it is concluded that the potential risk of workers from exposure to ethylene via inhalation, when used under the proposed conditions, is considered negligible.

Potential exposure to high concentrations of ethylene may occur in the event of a leak in an enclosed space. The proposed label includes precautionary statements regarding proper handling of cylinders and gas release system to avoid leaks; as well, the registrant would provide the user with access to information on proper equipment to use for releasing and monitoring ethylene gas. Respiratory protection for entry into an area of unknown ethylene concentration is recommended on the draft label. These precautionary statements are considered adequate.

Handling cylinders of compressed gas or any equipment under pressure represents a hazard due to its flammability and a potential for acute dermal or ocular exposure to the liquefied gas (i.e., it may cause frost burns if in contact with skin or eyes). This risk can be adequately mitigated with use of appropriate protective equipment; long sleeves, long pants, goggles or faceshield and appropriate gloves are considered adequate.

3.5.2 Bystanders

Based on the nature of the proposed use pattern of Eco Sprout Guard, there would be negligible potential for exposure of bystanders.

3.5.3 Workers

Workers may enter a storage area (e.g., for potato inspection) during or after treatment with ethylene before ventilation is complete (see section 3.5.1 for an assessment of worker potential exposure).

4.0 Residues

No residue data were submitted with this petition. However, previously submitted data and information in support of a former petition to register use of ethylene as a potato sprout inhibitor were summarized by the Health Protection Branch of Health Canada in May 1994 in the “Health and Safety Status Report” for ethylene. Information excerpted from this report is presented in this chapter.

Data provided indicate that the metabolism of ethylene, while not specifically elucidated in potatoes, is similar and probably identical to those metabolic pathways determined for ethylene metabolism in many plants. Potato tubers, as senescent tissues, exhibit low basal metabolic rates such that ethylene is metabolized very slowly, if at all. Endogenous concentrations of ethylene range between 0.0007–0.15 ppm for nonsprouting tubers and 0.1–3 ppm for sprouted tubers. These low concentrations of ethylene, combined with the low diffusion rates suggest that low concentrations of ethylene metabolites would be expected in stored tubers.

Ethylene and its potential metabolites were not identified in treated potatoes at levels exceeding those found in control potatoes, and therefore, animal metabolism and livestock feeding studies were not considered necessary for evaluation.

Residue data was provided for potatoes treated with 4 ppm ethylene for up to 150 days of storage. Residues of chloroethanol, dichloroethane, bromoethanol, ethylene oxide, and ethylene glycol (including its glucoside) residues were in total less than 0.1 ppm. Residues for the metabolite of greatest toxicological concern, ethylene oxide, were <2 ppm (the lower limit of quantitation (LLQ) of the analytical method employed). In addition, the processing or cooking of tubers is expected to result in a reduction of volatile residues (ethylene oxide) by up to 90%. This dissipation of residues would occur by diffusion out of potato tissues during processing of the tubers and by heat-assisted volatilization during cooking.

The partition coefficient for ethylene into potato tuber tissue is very low (0.207), indicating that there is little if any metabolism, compartmentalization of ^{14}C-ethylene by potato tubers or both. Typical soil atmospheres contain about 10 ppm endogenous ethylene levels that can increase as the moisture status of the soil increases. This indicates that developing potato tubers, which are metabolically active, might be expected to metabolize and bioaccumulate ethylene residues. This level of background exposure is 2.5 times greater than that proposed for supplementation of ambient storage bin atmospheres. No residues of ethylene metabolites (after correction for some measurable residues of ethylene glycol and its glucoside) were determined above LLQs in mature tubers for any treated potato tubers in the 1993 and 1994 research trial residue studies.

Evidence was presented that elucidated the impermeability of ethylene into potato tubers. Potato tubers have a high resistance to diffusion because the periderm of the tuber presents a barrier to gaseous diffusion and the bulk of the diffusion occurs through a very small area of the tuber, up to 2% of its volume. This condition effectively blocks movement of exogenous ethylene into the tuber (even against a concentration gradient) thereby maintaining internal concentrations of ethylene in the tuber at endogenous levels.

Processing studies were not performed for ethylene-treated potatoes. However, the processing of treated tubers into french fries, powdered potatoes, potato flour or cooking of raw potato tubers would reduce the residue of most concern, ethylene oxide, if it were present at levels above background. Ethylene oxide is a gas at room temperature and a liquid below 12EC. It would be expected to volatilize out of potatoes during cooking.

Based on the data submitted, residues in potatoes treated according to the proposed label directions will not result in residues of ethylene or its probable major metabolites above levels found in untreated potatoes. Therefore, no dietary risk assessment is considered necessary, and no MRLs are proposed.

5.0 Fate and behaviour in the environment

5.1 Physical and chemical properties relevant to the environment

The physicochemical properties of ethylene, summarized in Table 5.1, are based on a review conducted by the Laboratory Services Subdivision and other information gathered from various sources. Active ingredient purity was >98.5% in the reviewed studies.

Table 5.1 Physical and chemical properties relevant to the environment

Property	Value	Comments
Water solubility	22.6 mL/100 mL at 0EC; 12.2 mL/100 mL at 20EC	Sparingly soluble
Vapour pressure	4100 kPa at 0EC; 1063 kPa at 50EC	Product is a gas
log K_{ow} (25EC)	1.16	Bioaccumulation is not expected
Dissociation constant (pKa at 20EC)	Not applicable	No dissociable groups present in the active ingredient (a.i.)
UV / visible spectrum	Not expected to absorb UV at wavelength >300 nm	Photolysis is not expected to be route of dissipation in the environment

Summary of environmental chemistry and fate studies

No data were submitted or requested on the environmental fate of ethylene because this gas occurs naturally in the environment and the contribution from the proposed use will not be significant.

Expected environmental concentrations

Ethylene use in storage will only impact the expected environmental concentrations (EEC) of ethylene in the atmosphere; however, the contribution of ethylene from the proposed use site to atmospheric concentrations is considered to be negligible.

It is estimated that 89% of natural and anthropogenically produced ethylene gas is destroyed in the troposphere by OH^- radicals, and 8% is destroyed in reactions with ozone. Approximately 3% is transported into the stratosphere. Estimated lifetime in the atmosphere is approximately 2–4 days.

6.0 Effects on non-target species

No data were submitted or requested on effects to nontarget organisms because the contributions from the proposed use will not be significant. Adverse effects on nontarget organisms from the proposed use of ethylene, therefore, are not expected.

7.0 Efficacy

7.1 Effectiveness

7.1.1 Intended use

Eco Sprout Guard EP is intended for use on “Russet Burbank” potatoes in commercial storage facilities to inhibit sprout growth.

7.1.2 Mode of action

Ethylene is a plant growth regulator. In potatoes, ethylene has been documented to shorten the post-harvest rest period, resulting in earlier sprouting but inhibiting the elongation of sprouts by reducing apical dominance. Ethylene also enhances the abscission of sprouts.

7.1.3 Crops

Eco Sprout Guard EP is intended for use on stored “Russet Burbank” potatoes for processing.

7.1.4 Effectiveness against sprouting

Laboratory and commercial scale trials were conducted in which the efficacy of Eco Sprout Guard EP was assessed for the inhibition of sprouting in “Russet Burbank” processing potato tubers. In laboratory trials conducted from 1991–1992 to 1995–1996, Eco Sprout Guard EP was applied to tubers in barrels or steel cabinets to abruptly raise the concentration to 4 ppm once tubers had been permitted to cure (suberize) and cool to the final storage temperature of 9EC, about 8 weeks after the beginning of storage. A commercial standard treatment of chlorpropham (CIPC) was applied to tubers (dipped in 1% emulsion) in each trial.

No sprouting was observed in the CIPC treatment. In the ethylene treatment, the weight of large sprouts (>5 mm) was minimal or absent and ranged from 0 to 0.01 and from 0 to 0.5 g·kg^{-1} tuber fresh weight at 20 and 25 weeks after the initiation of application, respectively. In contrast, large sprout weight in the untreated control at 20 and 25 weeks ranged from 2.2 to 17.4, and from 8.5 to 38.5 g·kg^{-1} tuber fresh weight, respectively.

Sprout length increased over time but was always less for ethylene-treated tubers than untreated control tubers. Sprout length averaged 9 mm after 25 weeks of ethylene treatment whereas that in the untreated control averaged 204 mm.

Ethylene often increased number of small sprouts (2–5 mm) relative to the untreated control. At the biochemical and cellular level, continual ethylene exposure may have terminated rest (dormancy) in tuber eyes, possibly leading to an increase in sprout initiation while preventing excessive growth of these sprouts through the inhibition of cell differentiation and elongation. The force required to remove sprouts on ethylene treated potatoes was quantitatively assessed in the 1993–1994 trial and was determined to be significantly less than on untreated tubers.

In a laboratory trial conducted in 1997–1998, ethylene applied in accordance with the proposed application method resulted in sprouts that were less than 5 mm long at 33 weeks after the beginning of treatment. No sprouting was observed in the CIPC control treatment.

In commercial-scale trials conducted from 1992–1993 to 1994–1995, ethylene was applied to potato tubers to abruptly raise the ethylene concentration in the storage building to 4 ppm once tubers had been permitted to cure and cool to the final storage temperature of 9EC. In each trial, a commercial standard treatment of CIPC was applied once to cured tubers in a neighbouring storage building as an aerosol (Stanchem Sprout Nip 840). Ethylene reduced sprout number, sprout weight and sprout length. In 1992–1993, the longest sprout observed after 4 months of ethylene treatment was 2 mm, and total sprout weight averaged less than 0.01 g per tuber. No sprouting was observed in the CIPC treatment in this trial. In the trial conducted in 1993–1994, ethylene-treated tubers had higher sprout weight and sprout number than CIPC-treated tubers up until 22 weeks of storage. After this time, CIPC-treated tubers had large increases in sprout length and weight, such that by week 29, CIPC-treated tubers had about five times the sprout weight that ethylene-treated tubers had. CIPC residues are known to gradually decline over time, such that retreatment is often required to maintain sprout inhibition following 4–6 months of storage. In 1994–1995, it was stated in the trial report that a similar degree of sprout control was achieved with ethylene as in the previous 2 years and that sprout control was less than that achieved with CIPC. In the latter two trials, some sprouting was observed in CIPC treatment along the wall of the storage building, where it was likely CIPC did not reach the tubers. Ethylene is a lighter gas than CIPC applied as an aerosol, and therefore, ethylene is distributed more evenly throughout the storage pile than CIPC. The percentage of tubers with internal sprouts was lower for the ethylene treatment (0.01–0.05%) than for the CIPC treatment (0.5–0.7%).

In an additional commercial-scale trial conducted in 1998–1999, the degree of sprout inhibition was observed to be greater for the treatment of ethylene, applied in accordance with the proposed method, than for the CIPC treatment after 6 months of storage probably due to decreasing CIPC residues on tubers. At 6 months after the beginning of storage, about 17 and 48% of tubers treated with ethylene and CIPC had at least one sprout, respectively. By the final removal at 8 months, 37 and 56% of tubers treated with ethylene and CIPC, respectively, had at least one sprout. After 6 months of ethylene treatment, weight of small and large sprouts each averaged less than 1 g in tuber samples of approximately 35 kg, whereas the weight of small and large sprouts in CIPC-treated tubers averaged 3 and 7 g in similar-sized samples. After 8 months of ethylene treatment, the mean weight of small and large sprouts was about 17 and 42 g per 35 kg sample, respectively, whereas the mean weight of small and large sprouts of tubers treated with CIPC averaged 16 and 167 g, respectively. The mean maximum sprout length observed in ethylene-treated tubers was 6.5 and 27.5 mm at 6 and 8 months of storage, respectively, much shorter than the 45 and 122 mm observed for the CIPC treatment at these two evaluation times.

In each of the commercial trials, sprouts of ethylene-treated tubers were typically stunted, often branched and very brittle, such that these club-shaped sprouts easily fell off when the tubers were removed from storage.

7.2 Undesirable or unintended side effects on treated plant products

Potato tuber fry colour, as measured on an Agtron reflectance colorimeter (range of 0 = black to 100 = white), was assessed in the same laboratory trials in which efficacy was evaluated. In trials conducted from 1991–1992 to 1995–1996, fry colour generally improved (higher Agtron scale value) with storage time for all treatments. Tubers treated daily with 4 ppm ethylene were usually darker upon frying than either the untreated control or the CIPC treatment, which was related to higher reducing sugar levels in ethylene-treated tubers. At the 25-week evaluation date, relative fry colour among treatments was variable over years. Fry colour of ethylene-treated tubers was darker than untreated control tubers in two trials and darker than CIPC-treated tubers in three trials, was similar to that of CIPC-treated tubers in one trial and was lighter than CIPC-treated tubers in one trial. When averaged over the 5 years, ethylene-treated tubers had a lower Agtron value (by 7–10 points) than CIPC-treated tubers when assessed from 5 to 25 weeks. In the trial conducted in 1997–1998, ethylene was applied in accordance with the proposed application method to attain a maximum ethylene concentration of 4 ppm in the storage facility. The treatment evaluated in earlier trials was included for comparison along with a CIPC control. Fry colour of tubers treated with ethylene according to the proposed application method was 6–7 Agtron units darker than CIPC-treated potatoes from 18 to 33 weeks after the beginning of storage. In contrast, potato tubers treated with ethylene beginning at the end of the cooling period resulted in fry colour that was 19–25 Agtron units darker than that treated with CIPC. In an additional trial conducted in 1996–1997, ethylene applied in accordance with the proposed application method resulted in fry colour that was 15–22 Agtron units higher (lighter) than where ethylene had been applied at the end of the cooling period.

Fry colour was assessed in the same commercial-scale trials in which efficacy was evaluated. Fry colour of potato tubers randomly selected from the storage pile was assessed weekly in each of the trials conducted in 1992–1993, 1993–1994 and

1994–1995. Fry colour was generally darker in ethylene-treated tubers than in CIPC-treated tubers in all 3 years, regardless of when data were collected. Unlike the laboratory trials conducted from 1991–1992 until 1995–1996, fry colour did not improve over storage time for either of these treatments. Over the 26 weeks following the initiation of ethylene treatment, U.S. Department of Agriculture fry colour grade ratings (range of 1=light to 7=dark) for ethylene- and CIPC-treated tubers were 3.0 and 2.6 in 1992–1993, 3.4 and 2.8 in 1993–1994, and 2.5 and 1.7 in 1994–1995, respectively.

In the commercial-scale trial conducted in 1998–1999, potato tubers treated with ethylene applied in accordance with the proposed application method resulted in darker fry colour than CIPC after 3 and 6 months of storage. After 3 and 6 months of storage, the fry colour of tubers treated with ethylene were, respectively, 5 and 6 Agtron points lower on average than tubers treated with CIPC. Fry colour of ethylene-treated tubers and CIPC-treated tubers were similar after 8 months of storage.

7.3 Observations on undesirable or unintended side effects

Eco Sprout Guard EP is proposed for post-harvest use only on stored “Russet Burbank” potato tubers for processing in closed-system commercial storage facilities. It would not be expected to impact other crops. It would not be used on or near seed potatoes.

7.4 Economics

In 1998–1999, 4 292 000 t of potatoes were produced in Canada on 156 000 ha. Since 1992–1993, potato production has increased by 2–3% per year. In 1998, 620 000 t of potatoes were exported, mainly to the U.S. In that year, 30% of fresh exports were seed potatoes, and 70% were table stock potatoes and potatoes for processing. Approximately 50% of all potatoes grown in Canada are processed, much of which is exported as frozen french fries. In 1998, 483 436 t of frozen french fries valued at $461 million were exported, mainly to the U.S., but also to more than 90 countries worldwide. Between 1995 and 1998, the quantity and value of exported frozen french fries more than doubled. The importance of processed potato products to the Canadian economy is expected to continue to increase.

7.5 Sustainability

7.5.1 Survey of alternatives

7.5.1.1 Nonchemical control practices

Storage at very low temperatures (3 or 4EC) may be used to delay sprouting of potato tubers; however, these temperatures may induce high levels of reducing sugars, thereby resulting in fry colour of the processed product that is too dark to command top grades and prices.

7.5.1.2 Chemical control practices

Products containing maleic hydrazide or chlorpropham, listed in Table 7.5, are registered for control of sprouting in potatoes. There are two types of chlorpropham products: those that are applied as aerosols in the ventilation system of the potato storage building and those that are applied as emulsions to potatoes in the packing line. Products of the latter type are not typically used for processing potatoes and are not shown in Table 7.5.

Table 7.5 Alternative products for control of sprouting of stored processing potatoes

Active ingredient	End-use products	Mode of action	Application timing	Application rate
Maleic hydrazide	Royal MH 60SG (Reg. No. 18143)	Inhibits cell division	Applied in the field between 2–3 weeks past full bloom and 2 weeks before expected date of topkill or first frost, and when tubers are at least 4–5 cm in diameter	3.4 kg a.i./ha
Chlorpropham	Sprout Nip 840 (Reg. No. 18833)	Inhibits cell division	After harvesting, potatoes are allowed to cure (suberize) for at least 2 weeks before application	Sufficient product applied to achieve deposit of 6–12 ppm on potatoes
	Decco 273 Aerosol Potato Sprout Inhibitor (Reg. No. 24007)			For <4 months storage: 1 kg a.i./60 t potatoes; For 4–6 months storage: 2 kg a.i./50 t potatoes
	Clean Crop Spud-Nic Aerosol Grade (Reg. No. 24691)			For 3 months storage: 1.5–2 kg a.i./100 t potatoes; For 4–6 months storage: 3–3.75 kg a.i./100 t potatoes
	Ag-Services Potato Sprout Inhibitor (Fogging Grade) (Reg. No. 11848)			For 3 months storage: 1.5–2 kg a.i./100 t potatoes; For 4–6 months storage: 3–3.75 kg a.i./100 t potatoes
	Ag-Services 750A Potato Sprout Inhibitor (Fogging Grade) (Reg. No. 25834)			For 3 months storage: 1.5–2 kg a.i./100 t potatoes; For 4–6 months storage: 3–3.75 kg a.i./100 t potatoes

7.6 Conclusions

7.6.1 Summary

Data generated in laboratory and commercial-scale trials demonstrated that Eco Sprout Guard EP, when applied in accordance with the proposed method, can be expected to effectively inhibit sprouting of stored “Russet Burbank” processing potatoes while having minimal impact on processed product quality, such as fry colour. The accepted uses summarized in Table 7.6 are based on the value assessment.

Table 7.6 Summary of accepted use for Eco Sprout Guard EP

Crop	Potatoes (*Solanum tuberosum*)
Cultivar	Russet Burbank (for processing only)
Application timing	Throughout the storage period (up to 10 months)
Frequency of application	Daily during ventilation cycles
Application method	Applied from a pressurized gas cylinder into the ventilation airstream of the storage building to attain an ethylene concentration of up to 4 ppm.
Pest controlled	Sprouting

8.0 Toxic Substances Management Policy

Ethylene occurs naturally in the environment. The contribution from this use will not be significant. The technical grade ethylene does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track-1 substances. The end-use product, Eco Sprout Guard EP does not contain any U.S. Environmental Protection Agency List 1 formulants or formulants known to be TSMP Track-1 substances.

9.0 Proposed regulatory decision

The Pest Management Regulatory Agency (PMRA) has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient, pursuant to Section 18.b, to allow a determination of the safety, merit, and value of Eco Sprout Guard TGAI and Eco Sprout Guard EP, proposed for registration by McCain Foods Ltd. The PMRA has concluded that the use of Eco Sprout Guard TGAI and Eco Sprout Guard EP in accordance with the label has merit and value consistent with Section 18.c of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18.d. Therefore, based on the considerations outlined above, the use of Eco Sprout Guard TGAI and Eco Sprout Guard EP for the control of sprouting on stored “Russet Burbank” potatoes for processing is proposed for full registration, pursuant to Section 13 of the PCP Regulations.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed registration decision for this product.

List of abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CIPC	chlorpropham
d	day(s)
DNA	deoxyribonucleic acid
EEC	expected environmental concentration
EP	end-use product
EPA	U.S. Environmental Protection Agency
g	gram(s)
GC	gas chromatography
GRAS	generally recognized as safe
h	hour(s)
ha	hectare(s)
IARC	International Agency for Research on Cancer
K_{ow}	*n*-octanol/water partition coefficient
kg	kilogram(s)
kPa	kilo-Pascal(s)
L	litre(s)
LLQ	lower limit of quantitation
m	metre(s)
mL	millilitre(s)
mm	millimetre(s)
nm	nanometre(s)
nmol	nanomoles(s)
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PMRA	Pest Management Regulatory Agency
PRDD	proposed regulatory decision document
ppm	parts per million
t	tonnes
TGAI	technical grade active ingredient
TS	test substance
TSMP	Toxic Substances Management Policy
TWA	time-weighted average
UV	ultraviolet
FL	microlitre