Proposed Registration Decision PRD2010-26

1,4-Dimethylnaphthalene

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Overview

Proposed Registration Decision for 1,4-Dimethylnaphthalene

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of 1,4SIGHT Technical, 1,4SHIP, 1,4SIGHT and 1,4SEED, containing the technical grade active ingredient 1,4-dimethylnaphthalene, as a potato sprout inhibitor.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of 1,4SIGHT Technical, 1,4SHIP, 1,4SIGHT and 1,4SEED.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on 1,4-dimethylnaphthalene, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on 1,4-dimethylnaphthalene, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is 1,4-Dimethylnaphthalene?

1,4-Dimethylnaphthalene is a plant growth regulator belonging to the chemical family of alkyl-substituted naphthalenes. This compound is a naturally occurring plant biochemical in potatoes. It has been identified as a potato dormancy enhancer, delaying sprouting. The mode of action of 1,4-dimethylnaphthalene is unknown, but is likely hormonally based.

1,4SIGHT and 1,4SEED contain the active ingredient at 988 g/L and 998 g/L, respectively. 1,4SHIP contains 1,4-dimethylnaphthalene at 63.8% (equivalent to 96 g active ingredient per can). 1,4SIGHT and 1,4SEED are formulated as liquids (aerosol grade), while 1,4SHIP is formulated as a ready-to-use aerosol.

Health Considerations

Can Approved Uses of 1,4-Dimethylnapthalene Affect Human Health?

1,4-Dimethylnaphthalene is unlikely to affect human health when used according to label directions.

Exposure to 1,4-dimethylnaphthalene may occur when entering the treatment site during or after application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

1,4-Dimethylnaphthalene is of low acute toxicity by the oral, dermal, and inhalation routes. It is slightly irritating to eyes, mildly irritating to skin, and is not a skin sensitizer. Hazard statements alerting users to the irritation potential of 1,4-dimethylnaphthalene are required on the product labels. There is no information available in the published literature that suggests 1,4-dimethylnaphthalene is carcinogenic, genotoxic, neurotoxic or a developmental/reproductive toxicant.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is not of concern from the proposed uses of the formulations because 1,4-dimethylnaphthalene is a naturally occurring potato sprout inhibitor, has a low toxicity profile, and is naturally broken down. Moreover, residue levels are likely to be diminished further by washing, peeling and cooking.

These end-use products are proposed for use in a contained treatment area and not in proximity to water. No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling 1,4SHIP, 1,4SIGHT or 1,4SEED

Risks are not of concern when the products are used according to label directions, which include protective measures.

Due to the closed and automated nature of the application system, applicator exposure is expected to be minimal. Exposure during re-entry activities represents a high exposure scenario and the primary routes of exposure are inhalation and dermal, but exposures are well mitigated by precautionary measures, including the requirement for applicators to wear personal protective equipment and follow precautionary statements.

There is no bystander exposure expected from the proposed use pattern, as no people are allowed inside an enclosed storage facility during treatment.

Use directions and mitigative measures on the labels are considered adequate to protect individuals from any risks from occupational exposure.

Environmental Considerations

What Happens When 1,4-Dimethylnaphthalene Is Introduced Into the Environment?

Environmental risks are not of concern due to limited environmental exposure.

1,4-Dimethylnaphthalene is a chemical substance that occurs naturally in potatoes. 1,4-Dimethylnaphthalene is highly volatile and has a low solubility in water. It is expected to degrade rapidly in the environment through photochemical reactions (with hydroxyl radicals) or microbial activity. Environmental exposure from the indoor use of this product is expected to be limited.

1,4-Dimethylnaphthalene is not toxic to birds on an acute oral basis. Based on available data, there is no concern about inhalation risk to wild birds nesting or roosting in the vicinity of storage facilities. 1,4-Dimethylnaphthalene is toxic to aquatic organisms. However, based on the use patterns, no or very limited exposure of aquatic ecosystem is expected.

Value Considerations

What Is the Value of 1,4SHIP, 1,4SIGHT or 1,4SEED?

1,4-Dimethylnaphthalene is a naturally occurring plant biochemical in potatoes. It is applied to potatoes in storage as a dormancy enhancer, thus delaying sprouting along with reducing respiration and maintaining tuber firmness.

Effective sprout inhibition can be achieved with a single or multiple applications of 1,4-dimethylnaphthalene. 1,4-Dimethylnaphthalene is a volatile compound and can dissipate easily, requiring subsequent re-application in some situations. The effects of 1,4-dimethylnapthalene are reversible and, therefore, this product can be used on seed potatoes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of 1,4SHIP, 1,4SIGHT and 1,4SEED to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Signal wording and appropriate precautionary measures are required to address the mild skin irritation hazard. Hazard statements and appropriate precautionary measures are also required to address possible eye and respiratory irritation hazards.

Workers must wear coveralls over a long-sleeved shirt, long-pants, shoes, socks, protective eyewear, and chemical resistant gloves during application or during clean-up and maintenance activities. Storage areas must be ventilated for at least 30 minutes or completely ventilated before allowing workers to enter for normal activities. If entering storage areas before full ventilation, workers must wear coveralls over long-sleeved shirt, long-pants, shoes, socks, face-sealing goggles, chemical resistant gloves, and respiratory protection.

Environment

A hazard statement is required to address toxicity to aquatic organisms.

Value

An advisory statement is required to address possible yield reduction and shift to smaller tubers when the products are applied to seed potatoes. An advisory statement is also required to address the risk of undesirable taste characteristics in treated potatoes, which can be mitigated by monitoring residue levels to ensure they do not exceed 1 ppm prior to marketing.

Next Steps

Before making a final registration decision on 1,4-dimethylnaphthalene, the PMRA will consider all comments received from the public in response to this consultation document. The 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 Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

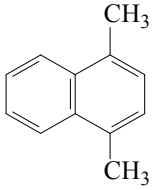
When the PMRA makes its registration decision, it will publish a Registration Decision on 1,4-dimethylnaphthalene (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

1,4-Dimethylnaphthalene

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	1,4-Dimethylnaphthalene
Function	Plant Growth Regulator
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	1,4-Dimethylnaphthalene
2. Chemical Abstracts Service (CAS)	1,4-Dimethylnaphthalene
CAS number	571-58-4
Molecular formula	$C_{12}H_{12}$
Molecular weight	156.23
Structural formula	
Purity of the active ingredient	98.4% nominal

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Products

Technical Product—1,4SIGHT Technical

Property	Result
Colour and physical state	Pale yellow liquid
Odour	Petroleum distillate odour
Melting range	N/A
Boiling point or range	264°C at 744 mmHg

Property	Result
Specific gravity at 25°C	1.014
Vapour pressure	Temp (°C) / Vapour pressure (Pa) 25 / 2.5 35 / 4.85 45 / 11.7
Henry's law constant at 25°C	7.558×10^{-4} atm·m^3/mole
Ultraviolet (UV)-visible spectrum	λ_{max} = 290 nm
Solubility in water at 25°C	5.1 ppm
Solubility in organic solvents at 20 ± 0.5°C	Solvent / Solubility (g/L) Methanol / > 250 Ethyl acetate / > 250 Acetone / > 250 n-Heptane / 239.5 1,2-Dichloroethane / 248.3 Xylene / 248.5
n-Octanol-water partition coefficient (K_{OW})	log K_{ow} = 4.372
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable to temperature and metals, but degrades when exposed to artificial light.

End-Use Products—1,4SHIP, 1,4SIGHT and 1,4SEED

Property	1,4SHIP	1,4SIGHT	1,4SEED
Colour	Pale yellow	Pale yellow	Pale yellow
Odour	Petroleum distillate odour	Petroleum distillate odour	Petroleum distillate odour
Physical state	Liquid	Liquid	Liquid
Formulation type	Pressurized product	Liquid	Liquid
Guarantee	63.8% nominal (limits: 62.9 – 66.7%) Equivalent to 96 g active ingredient per can	988 g/L (limits: 958-1018 g/L)	998 g/L (limits: 968-1028 g/L)
Container material and description	Metal aerosol can, 177 mL	Metal can, 20 L	Metal can, 20 L
Specific gravity at 25°C	0.85	1.014	1.014
pH	N/A	5.9	5.9
Oxidizing or reducing action	N/A	N/A	N/A

Property	1,4SHIP	1,4SIGHT	1,4SEED
Storage stability	Results of the study expected in February 2011	Stable when stored for 12 months at 25°C and 50% relative humidity in commercial packaging.	Stable when stored for 12 months at 25°C and 50% relative humidity in commercial packaging.
Corrosion characteristics	Not corrosive to the container material.	Not corrosive to the container material.	Not corrosive to the container material
Explodability	Not explosive	Not explosive	Not explosive

1.3 Directions for Use

1,4SIGHT, containing 1,4-dimethylnaphthalene at 988 g a.i./L, is applied to potatoes in storage to enhance dormancy. 1,4SEED, containing 1,4-dimethylnaphthalene at 998 g a.i./L, is applied alone to seed potatoes in storage to enhance dormancy. The products are applied alone at 10 or 20 ppm with multiple applications up to a cumulative maximum of 80 ppm. A minimum application interval of 30 days is required between treatments (Appendix I, Table 1).

1,4SHIP, containing 1,4-dimethylnaphthalene at 63.8% (equivalent to 96 g active ingredient per can), is applied alone to potatoes to enhance dormancy prior to transportation. Potatoes are treated with a single application of 10.6 ppm (10.6 mg active ingredient / kg potatoes) (Appendix I, Table 1).

1.4 Mode of Action

1,4-Dimethylnaphthalene is a plant growth regulator belonging to the chemical family of alkyl-substituted naphthalene. This compound is a naturally occurring plant biochemical in potatoes. The mode of action of 1,4-dimethylnaphthalene is unknown, but is likely hormonally based.

2.0 Methods of Analysis

The methods provided for the analysis of the active ingredient and the impurities have been validated and assessed to be acceptable for the determinations in the technical product and/or for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicological Summary

A detailed critical review of the submitted data and publicly available toxicological information for 1,4-dimethylnaphthalene was conducted. The submitted toxicology studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The database for 1,4-dimethylnaphthalene is complete, consisting of acute laboratory animal toxicity studies (oral, dermal and inhalation), skin and eye irritation studies, and a skin sensitization study. As well, a short-term oral toxicity study and genotoxicity studies were

provided. The submitted studies were conducted only with the technical grade active ingredient (TGAI) and used to support the data requirements of the associated end-use products. Although the PMRA requires toxicity and irritation studies to be conducted with all end-use product formulations, given that the end-use products contain no formulants of toxicological concern, testing with the TGAI to represent all the formulations was considered acceptable.

Studies specific to the metabolism of 1,4-dimethylnaphthalene are not available. Due its natural occurrence in potato tubers, humans are regularly exposed to 1,4-dimethylnaphthalene and, as such, are expected to have physiological pathways to metabolize this and other forms of dimethylnaphthalene.

Data on the acute toxicity and irritative effects of 1,4-dimethylnaphthalene are summarized in Appendix I, Table 2. Acute toxicity of 1,4-dimethylnaphthalene by oral, dermal and inhalation routes is low. In a primary eye irritation study in rabbits, 1,4-dimethylnaphthalene was minimally irritating to the eye. In a primary dermal irritation study in rabbits, 1,4-dimethylnaphthalene was mildly irritating to the skin. 1,4-Dimethylnaphthalene is not a skin sensitizer in guinea pigs when tested by the method of Buehler.

A short-term oral toxicity study showed no mortality at the highest dose tested (1000 mg/kg bw/d), but food consumption was significantly decreased in that dose group (Appendix I, Table 3). No treatment-related effects were observed in functional observational battery or motor activity assessments. Clinical chemistry analyses showed no biologically relevant alterations. Histopathology indicated kidney as the target organ, with males showing greater sensitivity than females. Chronic progressive nephropathy was noted in the high dose and basophilic tubules and mononuclear cells were observed in the mid-dose of 250 mg/kg bw/d male groups.

Three genotoxicity studies were submitted (Appendix I, Table 3). Based on results of *in vitro* bacterial reverse gene mutation (Ames) assay, *in vitro* unscheduled DNA synthesis in primary cell cultures, and the *in vivo* micronucleus assay, 1,4-dimethylnaphthalene is not considered genotoxic.

Submission of higher tier developmental and immunotoxicity as well as chronic (including carcinogenicity and reproduction) toxicity test data/information is only required if the potential for adverse chronic effects are indicated based on: 1) the short-term effect levels established in tier I short-term oral, dermal or inhalation studies; 2) the proposed use pattern of the end-use product(s); or 3) the expected frequency and level of repeated human exposure resulting from the proposed use of the end-use product(s). Based on a critical review of acute and short-term toxicity data on 1,4-dimethylnaphthalene, coupled with a long history of consumption of this compound as an ingredient in potatoes where it occurs as a natural sprout inhibitor with no reported adverse effects, there is no conclusive evidence to suggest that 1,4-dimethylnaphthalene is carcinogenic, mutagenic, immunotoxic, neurotoxic or is a reproductive toxicant. Moreover, the PMRA did not locate any reports of adverse effects from the consumption of potatoes treated with a synthetic form of this biochemical in countries where it is approved for a similar uses (United States, New Zealand).

3.2 Occupational Exposure and Risk Assessment

3.2.1 Use Description Scenario

The proposed use of the end-use products is to enhance dormancy of potatoes during storage or in transportation. 1,4SIGHT and 1,4SEED are to be used for storage sites and 1,4SHIP is to be used on potatoes in transportation containers (truck, rail car, shipping container, or cold storage room).

Storage site treatment of potatoes is done automatically with foggers (thermal aerosol applicators) and application sites are closed and not accessible to workers during the treatment. The recommended rate of application is 1 kg of active ingredient per 50,348 kg (15.6 mL/m3) potatoes, which is equivalent to 20 ppm on an active ingredient to potato basis. For effective dormancy control, reapplication is recommended which should not exceed the maximum application of 80 ppm during the storage season. Treatment of storage areas having circulating and non-circulating air systems have been proposed, and the labels suggest that it may be necessary to move the fogger during the application or make the application in multiple phases. A typical thermal aerosol application machine has a capacity of about 25 L/h, and a typical potato storage facility will hold approximately 1,814.37 tonnes, requiring 30 L at 16.53 mL/tonne. At a maximum rate of 20 mL/tonne, two storage facilities may be treated in a day by an applicator (73 L).

Transportation container treatment is to be made after potatoes are removed from storage, prepared for shipment, and placed either in truck, sea-going shipping container, rail car, or a cold storage room. 1,4SHIP is a ready-to-use formulation and no application equipment is required. The box(es) containing the can is to be adhered to an inside cargo wall; the cap of the can is removed and the trigger is depressed until it is locked and the can starts discharging the formulation continuously. The applicator is required to immediately vacate the treatment site, and close, seal and tag the entry door to the transportation container. Workers are not exposed when the can(s) are discharging. Re-entry is proposed 30 minutes after application, when the applicator enters the cargo area to remove the empty discharged can, and then the cargo is closed from human entry and set for transportation. At the maximum rate, a can (96 g active) will treat 9,000 to 10,000 kg of potatoes. It is recommended to use two cans per 18,000 to 20,000 kg of potatoes in trucks and shipping containers, six cans per 54,000 to 100,000 kg of potatoes in rail cars, and one can per 40 to 45 cubic metres and 9,000 to 10,000 kg of potatoes in cold storage rooms. For a small truck, one can is required. It may be possible for one worker to place 5-10 cans in an eight-hour work day.

After the aerosol fog has cleared in the large storage facilities, applicators first don their PPE and enter the building for clean-up and maintenance, which involves removing the discharge hose from the thermal fogging machine for storage. Further clean-up of the machine is done outside of the treatment area, which includes turning off the heater of the thermal fogging machine, and removing the pump hose from the container.

After the first re-entry for clean-up, there is a waiting period of 24 hours after which the ventilation system is turned on, doors of the closed treatment facility are opened and, after a minimum of at least 30 minutes or complete ventilation, normal operations are allowed.

3.2.2 Occupational Exposure

No mixing and loading is required since one product is a ready-to-use formulation and the other two products are applied automatically using specialized equipment (fogger). Applicators/ workers are to remain outside the enclosed treatment site during automated application. Due to the closed and automated nature of the application system, applicator exposure is expected to be minimal. Entry to the treatment sites during discharge is possible to move the location of the fogger. The only post application activity associated with the end-use products is the required clean-up after the fog has settled.

Exposure during entry or re-entry activities represents a high exposure scenario and the primary routes of exposure are inhalation and dermal, but occupational exposure to the end-use products will be minimal if applicators and related workers follow label recommendations. The product labels have a number of exposure reduction statements (e.g., the wearing of personal protective equipment, including long clothing, as well as hygiene statements) to protect workers from exposure while applying the products, during all clean-up/repair activities, and on post application re-entry.

3.2.3 Bystander

Non-workers are prohibited from entering potato storage facilities during product application, and potato storage facilities are typically located where bystanders cannot accidentally enter. Also, the products are to be applied by professional applicators and storage facilities are to be closed and sealed from bystander entry during application. The potential for bystander exposure is therefore expected to be minimal.

For use in potato shipping containers, cans of 1,4SHIP are placed inside the container and the doors are closed and sealed; bystanders are not present during this time. After application, the discharged product cans are removed by workers and the shipping container is re-sealed. Exposure to bystanders is not expected.

3.3 Food Residue Exposure Assessment

1,4-Dimethylnaphthalene is naturally present in potatoes as a plant growth regulator to inhibit potato sprouting. Natural concentrations can vary with the age and variety of the tuber and also depend on storage conditions. The maximum observed naturally occurring concentration for untreated tubers, based on residue trials submitted to the PMRA, was 0.5 ppm (measured in the peel).

Reapplication of the product has been reported to be necessary after one month due to the rapid decrease in concentration following application. Since repeated applications (up to four) may be required for enclosed storage areas and there is no minimum interval before treated potatoes can be marketed for human consumption, dietary exposure to residues of 1,4-dimethylnaphthalene is possible from the proposed use pattern.

Dietary risk to humans is not of concern from the proposed uses of the end-use products because 1,4-dimethylnaphthalene is a naturally occurring potato sprout inhibitor and has a low toxicity profile. In addition, 1,4-dimethylnaphthalene is gradually metabolized by the potatoes. In one study, 1,4-dimethylnaphthalene residues declined from 40-80 ppm to 0.05 ppm after 16 weeks of storage. Moreover, residue levels are likely to be diminished further by washing, peeling and cooking.

The PMRA did not locate any reports of adverse effects from dietary exposure to 1,4-dimethylnaphthalene from the countries where the technical active is currently registered for similar uses (United States, New Zealand).

The end-use products are proposed for use in a contained treatment area and not in proximity to water. No risk due to exposure from drinking water is anticipated.

The risk from dietary exposure to potatoes from the use of 1,4-dimethylnaphthalene formulations is considered negligible; therefore, a quantitative food residue exposure assessment was not required and no additional residue data are required.

3.3.1 Acute and Chronic Dietary Risks for Sensitive Subpopulations

When used according to label directions, 1,4SHIP, 1,4SIGHT and 1,4SEED are not expected to result in 1,4-dimethylnaphthalene residues at concentrations of toxicological concern. Also, 1,4-dimethylnaphthalene is not stable and naturally degrades.

Currently, there are no other registered pesticidal uses of 1,4-dimethylnaphthalene. Moreover, exposure of the general population and potentially sensitive subpopulations, including infants and children, to 1,4-dimethylnaphthalene residues are further diminished by washing, peeling and cooking of potatoes before consumption.

3.3.2 Maximum Residue Limits

Dietary risk to humans is not of concern from the proposed uses of the end-use products because 1,4-dimethylnaphthalene is a naturally occurring potato sprout inhibitor, has a low toxicity profile, is not stable, and naturally degrades. Moreover, residue levels are likely to be diminished further by washing, peeling and cooking. Since it is not possible to distinguish 1,4-dimethylnaphthalene residues on potatoes from the use of the end-use products from natural background levels of 1,4-dimethylnaphthalene, the establishment of a maximum residue limit will not be required for 1,4-dimethylnaphthalene. Therefore, the use of 1,4SIGHT, 1,4SEED and 1,4SHIP to enhance inhibition of potato sprouts is not expected to result in unacceptable dietary risks when the products are used according to label instructions, and when potatoes are consumed after washing, peeling and cooking.

In the United States, 1,4-dimethylnaphthalene is exempted from the requirement of a food tolerance. Also, in New Zealand a proposal to exempt 1,4-dimethylnaphthalene has been made because residues in potatoes from the use of formulations containing 1,4-dimethylnaphthalene cannot be distinguished from natural background levels.

3.4 Aggregate Exposure

The potential for dietary exposure of the general public to 1,4-dimethylnaphthalene residues resulting from the proposed use of 1,4SHIP, 1,4SIGHT and 1,4SEED as sprout inhibitors of potatoes is not expected to be of toxicological concern, considering the low toxicity profile of 1,4-dimethylnaphthalene. Dietary exposure is likely from the use of the proposed end-use products, but is not considered a significant risk because residue levels are likely to be diminished by washing, peeling and cooking; thereby, resulting in low dietary exposure.

Exposure via drinking water is not expected to occur from this use. Non-occupational (i.e., residential) exposure is not expected to occur as a result of this use because there are no residential uses or any other registered uses for 1,4-dimethylnaphthalene.

The general public is exposed to 1,4-dimethylnaphthalene by virtue of its natural occurrence in potatoes. Given that no appreciable increase in dietary exposure relative to background levels is expected to occur from the use of 1,4-dimethylnaphthalene when potatoes are consumed after washing, peeling and cooking, the PMRA has determined that there is no unacceptable risk expected from the aggregate exposure to 1,4-dimethylnaphthalene.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

As per Regulatory Proposal PRO2007-02, *Guidelines for the Registration of Low-Risk Biochemicals and Other Non-Conventional Pesticides,* no environmental fate data are required for 1,4-dimethylnaphthalene. 1,4-Dimethylnaphthalene is an organic volatile that occurs naturally in potato skins. In the terrestrial environment, 1,4-dimethylnaphthalene is expected to volatilize from dry, wet or moist surfaces. When applied, 1,4-dimethylnaphthalene is expected to

be gradually metabolized by the potatoes. After dissipation into the atmosphere, 1,4-dimethylnaphthalene is expected to be degraded through photochemical reactions with the hydroxyl (OH) radicals. Once in the soil, 1,4-dimethylnaphthalene will not leach from the seed potatoes due to its low solubility in water. Accumulation of 1,4-dimethylnaphthalene in soil is unlikely due to its rapid microbial degradation. Based on the use pattern, no or very limited exposure of aquatic ecosystem is expected.

4.2 Risks to Non-Target Species

As per Regulatory Proposal PRO2007-02, *Guidelines for the Registration of Low-Risk Biochemicals and Other Non-Conventional Pesticides,* no environmental toxicity data are required under Tier I for indoor use (storage facility). However, inhalation risk to wild birds that could be acutely exposed to escaped fumes once the enclosed treated facility is opened was assessed. Use of products containing 1,4-dimethylnaphthalene on stored potatoes or seed potatoes at the maximum cumulative application rate of 80 mg a.i./kg potatoes is not expected to result in inhalation exposure of wild birds nesting or roosting in the vicinity of storage facilities (when enclosed storage facility is opened or ventilated). Therefore, negligible risk to birds is expected. Information on acute and chronic toxicity of 1,4-dimethylnaphthalene to daphnia, fish and two studies on aquatic plants were available. 1,4-Dimethylnaphthalene was toxic to aquatic organisms (Appendix I, Table 4), but given the use pattern, no or very limited exposure of aquatic ecosystem is expected; therefore no aquatic risk assessment was conducted. Any use expansion involving an outdoor application may require a further assessment of the risks, including other toxicity data.

5.0 Value

5.1 Effectiveness Against Pests

In support of the registration of 1,4SIGHT and 1,4SEED, relevant efficacy data were submitted from 19 trials, conducted from 1995 to 2007 in the following countries: United Kingdom, New Zealand, Australia, Germany, the Netherlands, France, United States, and Canada. Rates assessed ranged from 5 ppm to 60 ppm, applied as a single or as multiple applications. The treatments were applied using aerosol generating equipment (either as a cold fog or hot fog) or aqueous spray (one trial only).

The efficacy of 1,4SIGHT and 1,4SEED as a dormancy enhancer was assessed as sprouting inhibition, prevention of weight loss, and maintenance of tuber firmness. Treated tubers were compared to an untreated check or a commercial standard. The data support the claims summarized in Appendix I, Table 1.

No efficacy data were provided in support of the registration of 1,4SHIP. Unlike 1,4SIGHT and 1,4SEED, where storage facilities must remain sealed for 24 hours after treatment, shipping containers may be re-opened after a minimum of 30 minutes. Given that only short-term sprouting delay is required in this situation, it is expected that 1,4SHIP will provide adequate sprouting delay. The product must be applied alone. The data support the claims summarized in Appendix I, Table 1.

5.2 Adverse Effects to Target Plant Products

Data from a total of 23 non-safety adverse effects (NSAE) trials were submitted in support of the registration of 1,4SIGHT. Twenty-one reported one or more of the following NSAE data: sensory (taste) test and/or residue analysis, fry colour, sprout quality or burning, frequency of various diseases, and sugar content. The remaining two of the 23 NSAE trial reports, provided data regarding the subsequent crop from seed potatoes treated with 1,4-dimethylnaphthalene. The parameters examined included crop emergence, # tubers per plant, # stems/plant, emergence height, yield, and tuber size distribution.

Fry colour, sprout quality, the occurrence of various diseases and sugar content was acceptable. A reduction in yield and a shift to smaller tubers was observed in the subsequent crop issued from treated seed potatoes, thus necessitating an advisory statement on the label. The sensory threshold for 1,4-dimethylnaphthalene in potatoes is 0.8 – 1.4 ppm. In seven of the 14 trials for which residue data were provided, the residue levels exceeded the threshold even when taking into consideration the effect of processing. Thus an advisory statement regarding the negative effects on taste characteristics was required.

The NSAE data provided in support of the registration of 1,4SIGHT was also used to support the registration of 1,4SEED.

No NSAE data were provided in support of 1,4SHIP. However, given that only that a single application of 1,4SHIP at 10.6 ppm would be required in a shipping container, it is expected that any NSAE would not be greater that that observed with 1,4SEED and 1,4SIGHT.

5.3 Economics

Potatoes are the most valuable vegetable crop in Canada, accounting for 33% of all vegetable farm cash receipts. In Canada, potatoes are grown in all ten provinces on over 150,000 hectares of land, with the national production reaching 4.7 million metric tonnes in 2008. In 2008 the 4.7 million metric tonnes of potatoes harvested generated approximately 1.2 billion dollars for the Canadian potato industry.

Potatoes are stored indoors under controlled conditions. The purpose of storage is to maintain tubers in edible and marketable conditions and to allow a uniform flow of potatoes to market and processing plants throughout the year. Potato innate dormancy is a physiological stage during which potato tubers are not able to sprout, even under favourable growth conditions. 1,4-Dimethylnaphthalene is a potato dormancy enhancer, extending the dormancy period, thus providing greater flexibility in the flow of potatoes to market and processing.

5.4 Sustainability

5.4.1 Survey of Alternatives

Currently in Canada, chlorpropham (CIPC) and ethylene are the only registered active ingredients for use on potatoes in storage for sprout inhibition. Unlike 1,4-dimethylnaphthalene, CIPC cannot be used on seed potatoes as tubers treated with CIPC will not sprout.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Under ideal storage conditions tubers can be stored up to 10 months. Ideal storage conditions include maintaining appropriate temperatures, maintaining a high relative humidity, providing oxygen for respiration and removing carbon dioxide. The use of 1,4-dimethylnaphthalene is compatible with such practices.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Given that 1,4-dimethylnaphthalene is a naturally occurring compound in potatoes, development of resistance is not expected.

5.4.4 Contribution to Risk Reduction and Sustainability

The availability of 1,4-dimethylnaphthalene provides an alternative sprout inhibitor option and mode of action to the commonly used CIPC.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, 1,4-dimethylnaphthalene was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- 1,4-Dimethylnaphthalene does not meet all Track 1 criteria and is not expected to form any transformation products that are Track 1 substances. 1,4-Dimethylnaphthalene is a naturally occurring substance and is not expected to persist or bioaccumulate in the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade 1, 4-dimethylnaphthalene and the end-use products 1,4SHIP, 1,4SIGHT and 1,4SEED do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[9].

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

8 DIR2006-02, PMRA Formulants Policy.

9 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

The available information for 1,4-dimethylnaphthalene is adequate to qualitatively identify the toxicological hazards that may result from exposure to 1,4-dimethylnaphthalene. 1,4-Dimethylnaphthalene is of low acute toxicity by oral, dermal and inhalation routes. It is mildly irritating to skin, minimally irritating to eyes, and is not considered a skin sensitizer. There is no information available in the published literature that suggests 1,4-dimethylnaphthalene is carcinogenic, genotoxic, neurotoxic or a developmental/reproductive toxicant.

Mixing and loading are not required for any of the three end-use products. Due to the closed and automated nature of the application system, applicator exposure is expected to be minimal. There is potential for exposure during entry or re-entry to treatment sites prior to ventilation or prior to settling of aerosol fog. There is no bystander exposure. Occupational exposure to the proposed end-use products is expected to be minimal if the precautionary statements and recommended personal protective equipment on the product labels, which are intended to minimize worker exposure, are observed.

Dietary risk to humans is not of concern because 1,4-dimethylnaphthalene is a naturally occurring potato sprout inhibitor with a low toxicity profile, and there is anticipated low dietary exposure when potatoes are consumed after washing, peeling and cooking.

7.2 Environmental Risk

Based on the use patterns of 1,4SHIP, 1,4SIGHT and 1,4SEED, which include direct application as an aerosol into closed shipping containers or enclosed storage spaces filled with potatoes, 1, 4-dimethylnaphthalene presents a negligible risk to wild birds nesting or roosting in the vicinity of storage facilities. Environmental exposure is expected to be minimal.

7.3 Value

There is adequate evidence to support the claims for using 1,4SHIP, 1,4SIGHT and 1,4SEED as dormancy enhancers for stored potatoes or seed potatoes. The products provide sprouting inhibition, while preventing weight loss and maintaining tuber firmness. The products are not expected to adversely affect fry colour, sprout quality, the occurrence of various diseases or sugar content. A reduction in yield and a shift to smaller tubers was observed in the subsequent crop issued from treated seed potatoes, thus necessitating an advisory statement on the labels. An advisory regarding the negative effects of high levels of 1,4-dimethylnaphthalene on taste characteristics are also required. 1,4SIGHT provides an alternative mode of action to the commonly used CIPC (chlorpropham).

7.4 Unsupported Uses

Certain claims originally proposed by the applicant were not supported because the value was not adequately demonstrated.
Unsupported claims for 1,4SIGHT and 1,4SEED included:

- more vigorous seed growth;
- enhances the potato's ability to heal cuts and bruises;
- reduces refrigeration and ventilation needs;
- reduces pressure bruising; and/or
- improved visual appearance.

All claims were supported for 1,4SHIP, which did not include the claims listed above for 1,4Seed and 1,4SIGHT.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of 1,4SIGHT Technical, 1,4SHIP, 1,4SIGHT and 1,4SEED, containing the technical grade active ingredient 1,4-dimethylnaphthalene, as a potato sprout inhibitor.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

°C	degree(s) Celsius
µg	microgram(s)
a.i.	active ingredient
atm	atmosphere(s)
bw	body weight
CAS	Chemical Abstracts Service
CIPC	chlorpropham
CPN	chronic progressive nephropathy
d	day(s)
DNA	deoxyribonucleic acid
EC50	effective concentration 50%
ErC50	effective concentration 50% based on growth rate
EyC50	effective concentration 50% based on yield
EbC50	effective concentration 50% based on growth (biomass)
g	gram(s)
h	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
Kow	*n*–octanol-water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
m	metre(s)
mg	milligram(s)
mL	millilitre(s)
mmHg	millimetre(s) of mercury
MAS	maximum average score
MIS	maximum irritation score
MRL	maximum residue limit
N/A	not applicable
nm	nanometre(s)
NOAEL	no observed adverse effect level
NSAE	non-safety adverse effects
Pa	pascal(s)
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	Personal protective equipment
ppm	parts per million
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Rates of Application and Acceptable Efficacy Claims for 1,4SHIP, 1,4SIGHT and 1,4SEED

Product	Application Rate	Efficacy Claims	Comments
1,4SIGHT	10 - 20 ppm	Potato dormancy enhancer. Delays sprouting, along with maintaining tuber firmness and reducing respiration, resulting in less water loss.	The lower rate may be sufficient: for adequately filled stores (< 50% headspace) and storage temperatures between 3 and 8ºC, storage facilities with little outside ventilation, or facilities that are well sealed. At both rates, re-application needs to take place as required based on regular monitoring and observed movement/development of budding sprouts. The first application of 1,4SIGHT can be made at any time after the potatoes are placed in the storage area, but prior to sprouting. Subsequent re-treatment is only required if visual inspection indicates eye opening. Allow a minimum of 1 month between treatments. Do not exceed 80 ppm during the storage season. A 60 day interval is required between exposure of seed potatoes to 1,4-dimethlynaphthalene and planting.
1,4SEED	10 - 20 ppm	Potato dormancy enhancer. Delays sprouting, along with maintaining tuber firmness and reducing respiration, resulting in less water loss.	The lower rate may be sufficient: for adequately filled stores (< 50% headspace) and storage temperatures between 3 and 8ºC, storage facilities with little outside ventilation, or facilities that are well sealed. At both rates, re-application needs to take place as required based on regular monitoring and observed movement/development of budding sprouts. The first application of 1,4SEED can be made at any time after the potatoes are placed in the storage area, but prior to sprouting. Subsequent re-treatment is only required if visual inspection indicates eye opening. Allow a minimum of 1 month between treatments. Do not exceed 80 ppm during the storage season. A 60 day interval is required between exposure of seed potatoes to 1,4-dimethlynaphthalene and planting.
1,4SHIP	10.6 ppm	Potato dormancy enhancer. Delays sprouting, along with maintaining tuber firmness and reducing respiration, resulting in less water loss.	Apply after area to be treated has been loaded. Do not re-apply. A 60 day interval is required between exposure of seed potatoes to 1,4-dimethlynaphthalene and planting.

Table 2 Acute Toxicity and Irritative Effects of 1,4-Dimethylnaphthalene (94.7% purity)

Study Type	Species	Result	Comment	Reference
Oral	Rat	LD_{50} = 2730 mg/kg bw with 95% Confidence Limits of 2346 to 3178 mg/kg	Low acute toxicity	1723548 1723549
Dermal	Rabbits	LD_{50} > 2000 mg/kg bw	Low acute toxicity	1723551
Inhalation	Rats	LC_{50} > 4.16 mg/L	Low acute toxicity	1723552
Skin irritation	Rabbits	MAS[a] = 2.5/8 MIS[b] = 3.3/8	Skin irritant Mildly irritating	1723554
Eye irritation	Rabbits	MAS =7.44/110 MIS = 8.67/110	Minimally irritating to eyes	1723553
Skin sensitization[c]	Guinea pig	Negative results	Negative skin sensitizer	1723555

[a] Maximum average score according to the method of Draize (MAS)
[b] Maximum irritation score according to the method of Draize (MIS)
[c] Buehler method.

Table 3 Short-term Toxicity and Genotoxicity Profile of 1,4-Dimethylnaphthalene (94.7% purity)

Study Type	Species	Results (mg/kg/d in M/F)	Reference
Short-term oral toxicity	Rats	Dose: 0, 50, 250, and 1000 (target dose) mg/kg bw/d for 7 days a week for 90 days. No mortality. Treatment related clinical signs consisted of discoloured inguinal fur in high-dose males. Histopathology indicated kidney as the target organ. Chronic progressive nephropathy (CPN) was noted in the high dose males, and basophilic tubules and mononuclear cells were seen in the 250 mg/kg/d males. The incidence of kidney effects was greater in males than females. After the recovery period, the kidney effects persisted in 6 of 10 high–dose males. NOAEL for 1,4-dimethylnaphthalene was 50 mg/kg/d.	1723557
Genotoxicity			
Micronucleus assay (*in vivo*)	Mice	Dose: 225, 450, and 900 mg/kg (test substance in corn oil) No significant increase in micronucleui in bone marrow polychromatic erythrocytes. Negative results Not genotoxic	1723561 1723559

Study Type	Species	Results (mg/kg/d in M/F)	Reference
Genotoxicity test, *in vitro*: Unscheduled DNA synthesis	Rat liver primary cell cultures	Dose: 100 to 0.00250 µg/mL in the presence of 10 µCi/mMole No significant increase in net nuclear grain counts at the concentrations tested Negative results Non-mutagenic	1723558
Reverse gene mutation assay (Ames Assay)	*S. typhimurium* (TA98, TA100, TA1535, TA1537, and TA1538)	Dose: 6 doses: 10, 50, 100, 250, 500, and 1000 µg/plate in the presence of S9 mix, and from 1.00 to 250µg/plate (5 doses) in the absence of S9 mix. Negative results Non-mutagenic	1723560

Table 4 Acute toxicity of 1,4-dimethylnaphthalene (96.4-98.8% purity) to non-target aquatic species

Organism	Endpoint value (mg a.i./L)	Degree of toxicity[a]	Reference
Invertebrate			
Water flea *(Daphnia magna)*	48h $EC_{50:}$ 0.54	Highly toxic	1726519
Fish			
Rainbow trout *(Oncorhynchus mykiss)*	96h LC_{50} : 0.67	Highly toxic	1726523
Fathead minnow *(Pimephales promelas)*	96h LC_{50} : 1.4	Moderately toxic	1726524
Plants			
Green algae *(Selenanastrum capricornutum)*	96h E_bC_{50}: 0.33 96h E_yC_{50}: 0.34 96h E_rC_{50}: 0.60	Not applicable	1726525
Duckweed *(Lemna gibba)*	7d E_yC_{50}: 1.1	Not applicable	1726521

[a] USEPA classification

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1723534
Reference: 1993, USEPA chemistry package, Data Numbering Code: 2.0 Confidential Business Information

PMRA Document Number: 1723535
Reference: 2009, Chemistry requirements, Data Numbering Code: 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 Confidential Business Information

PMRA Document Number: 1723536
Reference: 2000, Starting materials, Data Numbering Code: 2.11.2 Confidential Business Information

PMRA Document Number: 1723537
Reference: 2001, Manufacturing process for 1,4-dimethylnaphthalene, Data Numbering Code: 2.11.3 Confidential Business Information

PMRA Document Number: 1723538
Reference: 2000, Analysis of samples – five batches of 1,4-dimethylnaphthalene, Data Numbering Code: 2.13.3 Confidential Business Information

PMRA Document Number: 1723539
Reference: 2009, Chemical and physical properties, Data Numbering Code: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9 Confidential Business Information

PMRA Document Number: 1723540
Reference: 1993, 1,4-DMN solubility, Data Numbering Code: 2.14.7 Confidential Business Information

PMRA Document Number: 1723541
Reference: 2005, Determination of the solubility of 1,4-dimethylnaphthalene in organic solvents by the shake flask method, Data Numbering Code: 2.14.8 Confidential Business Information

PMRA Document Number: 1723542
Reference: 1993, 1,4-DMN vapour pressure, Data Numbering Code: 2.14.9 Confidential Business Information

PMRA Document Number: 1723543
Reference: 1994, 1,4-DMN batch H5510 – Corrosion characteristics, Data Numbering Code: 2.14.13 Confidential Business Information

PMRA Document Number: 1723544
Reference: 1995, 1,4-DMN – Storage stability, Data Numbering Code: 2.14.14 Confidential Business Information

PMRA Document Number: 1723545
Reference: 1993, 1,4-DMN – Stability, Data Numbering Code: 2.14.14 Confidential Business Information

PMRA Document Number: 1726514
Reference: 2009, Chemistry information, Data Numbering Code: 3.2, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.7, 3.5.9 Confidential Business Information

PMRA Document Number: 1798945
Reference: 2009, Clarification on chemistry information, Data Numbering Code: 2.11.2, 2.11.4, 2.13.1, 2.14.12 Confidential Business Information

2.0 Human and Animal Health

PMRA Document Number: 1723547
Reference: 2009, Studies conducted to support registration of 1,4-dimethylnaphthalene, Data Numbering Code: 4.1

PMRA Document Number: 1723548
Reference: 1993, Acute oral toxicity stud of 1,4-dimethylnaphthalene (1,4-DMN) in rats, Data Numbering Code: 4.2.1

PMRA Document Number: 1723549
Reference: 1993, Acute oral toxicity stud of 1,4-dimethylnaphthalene (1,4-DMN) in rats (limit test), Data Numbering Code: 4.2.1

PMRA Document Number: 1723551
Reference: 1993, Acute dermal toxicity study of 1,4-dimethylnaphthalene (1,4-DMN) in rabbits (limit test), Data Numbering Code: 4.2.2

PMRA Document Number: 1723552
Reference: 1993, Acute inhalation toxicity study of 1,4-dimethylnaphthalene (1,4-DMN) in rats, Data Numbering Code: 4.2.3

PMRA Document Number: 1723553
Reference: 1993, Primary eye irritancy study of 1,4-dimethylnaphthalene (1,4-DMN) in rabbits, Data Numbering Code: 4.2.4

PMRA Document Number: 1723554
Reference: 1993, Acute dermal irritancy/ corrosivity study of 1,4-diemethylnaphthalene (1,4-DMN) in rabbits, Data Numbering Code: 4.2.5

PMRA Document Number: 1723555
Reference: 1993, Dermal sensitization study of 1,4-dimethylnaphthalene (1,4-DMN) in Guinea pigs using the modified Buehler method, Data Numbering Code: 4.2.6

PMRA Document Number: 1723556
Reference: 1993, 1,4-DMN hypersensitivity incident reporting, Data Numbering Code: 4.2.9

PMRA Document Number: 1723557
Reference: 2004, 90-Day oral (diet) toxicity study of 1,4-dimethylnaphthalene in rats, Data Numbering Code: 4.3.1

PMRA Document Number: 1723558
Reference: 1993, Genotoxicity test on 1,4-dimethylnaphthalene in the assay for unscheduled DNA synthesis in rat liver primary cell cultures, Data Numbering Code: 4.5.4

PMRA Document Number: 1723559
Reference: 2007, *In vivo* mouse bone marrow slide scoring for the micronucleus assay, Data Numbering Code: 4.5.4

PMRA Document Number: 1723560
Reference: 1993, Mutagenicity test on 1,4-dimethylnaphthalene in the *Salmonella*/ mammalian-microsome reverse mutation assay (Ames test), Data Numbering Code: 4.5.4

PMRA Document Number: 1723561
Reference: 1993, Mutagenicity test on 1,4-dimethylnaphthalene ~~in vivo~~ mouse micronucleus assay, Data Numbering Code: 4.5.5

PMRA Document Number: 1723565
Reference: 1995, EPA Tolerance Exemption, Data Numbering Code: 12.5

PMRA Document Number: 1723567
Reference: USEPA, 1995, Pesticide fact sheet: 1,4-Dimethylnaphthalene, Data Numbering Code: 12.5

PMRA Document Number: 1726516
Reference: 2002, Analytical method verification for the determination of 1,4-dimethylnaphthalene in algal medium, Data Numbering Code: 7.2.2

PMRA Document Number: 1726517
Reference: 1993, Validation of Methodology for the Residue Analysis of 1, 4-Dimethylnaphthalene in Potato Tubers, Data Numbering Code: 7.2.2

PMRA Document Number: 1726531
Reference: Baker A, 1997, Use of natural sprouting inhibitors for potato storage, Horticultural Research & Development Corporation, Gordon, NSW, Australia, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726515
Reference: Use Description, Data Numbering Code: 5.2

3.0 Environment

PMRA Document Number: 1723548
Reference: 1993, Acute oral toxicity of 1,4-dimethylnaphthalene (1,4-DMN) in rats, Data Numbering Code: 4.2.1

PMRA Document Number: 1723566
Reference: US EPA, 1995, 1,4-Dimethylnaphthalene; exemption from the requirement of a tolerance. Federal Register / Vol. 60, No. 26 / Wednesday, February 8, 1995 / Rules and Regulations, page 7456-7457, Data Numbering Code: 12.5

PMRA Document Number: 1726518
Reference: 2009, Studies conducted to support the registration of 1,4-dimethylnaphthalene, Required tests for low-risk technical grade active ingredient biochemical pesticides and low-risk end use products, Data Numbering Code: 9.1

PMRA Document Number: 1726519
Reference: 1993, 1,4-Dimethylnaphthalene – Acute toxicity to daphnids (*Daphnia magna*) under flow-through conditions, Data Numbering Code: 9.3.2

PMRA Document Number: 1726521
Reference: 1993, 1,4-Dimethylnaphthalene – Acute toxicity to daphnids (*Daphnia magna*) under flow-through conditions, Data Numbering Code: 9.3.2

PMRA Document Number: 1726523
Reference: 1993, 1,4-Dimethylnaphthalene – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions, Data Numbering Code: 9.5.2.1

PMRA Document Number: 1726524
Reference: 2002, 1,4-Dimethylnaphthalene: A 96-hour static-renewal acute toxicity test with the fathead minnow (*Pimephales promelas*), Data Numbering Code: 9.5.2.3

PMRA Document Number: 1726525
Reference: 2002, 1,4-Dimethylnaphthalene: A 96-hour toxicity test with the freshwater alga (*Selenastrum capricornutum*), Data Numbering Code: 9.5.2.3

PMRA Document Number: 1726526
Reference: 1993. Acute oral LD_{50} with bobwhite quail (*Colinus virginianus*) using 1,4-dimethylnaphthalene (1,4-DMN), Data Numbering Code: 9.6.2.1

4.0 Value

PMRA Document Number: 1726527
Reference: 2009, Value summary, mode of action, description of pest problem, Data Numbering Code: 10.2.1, 10.2.2

PMRA Document Number: 1726528
Reference: 2009, Preliminary tests – efficacy, Data Numbering Code: 10.2.3.1

PMRA Document Number: 1726529
Reference: 2008, Potential 1,4 Sight storage treatment efficacy studies for biological dossier 1× 10 ppm application, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726531
Reference: Baker A, 1997, Use of natural sprouting inhibitors for potato storage, Horticultural Research & Development Corporation, Gordon, NSW, Australia, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726532
Reference: 2005, Post harvest chemical trial 2004, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726535
Reference: Boylston TD, Powers JR, Weller, KM, Yang J, 2001, Comparison of sensory differences of stored russet burbank potatoes treated with CIPC and alternative sprout inhibitors, Amer J of Potato Res 78: 99-107, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726536
Reference: 2000, Evaluation of the efficacy of 1,4-DMN sprout suppressant, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726538
Reference: 2001, Evaluation of the efficacy of 1,4-DMN sprout suppressant, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726539
Reference: 2002, Evaluation of the efficacy of 1,4-DMN sprout suppressant, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726541
Reference: 2001, lmproving seed potato production, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726550
Reference: 1998, Dimethyl-naphthalene as a post-harvest sprout inhibitor for stored potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726552
Reference: 2004, The impact of common processing methods on 1,4-dimethylnaphthalene residues in potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726553
Reference: 2004, Sprout control efficacy of 1,4-DMN, the Netherlands 2002/2003 storage season, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726554
Reference: 2004, Sprout control efficacy of 1,4-DMN, Germany 2003/2004 storage season, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726560
Reference: 2004, Evaluation of the residue levels of stored potato tubers treated with 1,4-DMN, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726562
Reference: Knowles NR, Knowles, LO, Haines MM, 2005, 1,4-Dimethylnaphthalene treatment of seed potatoes affects tuber size distribution, Amer J of Potato Res 82: 179-190, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726564
Reference: 2005, Report on the effect of 1,4 DMN (1,4-dimethylnaphthalene) potato dormancy enhancer, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726565
Reference: 2003, Efficacite antigerminative sur pomme de terre d'une nouvelle molecule proposee par la societe D-I-1-4 Inc (Potatoe sprout control efficacy of a new molecule proposed by D-I-1-4 Inc), Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726566
Reference: 1996, Evaluation of 1,4-dimethyl naphthalene for the control of sprouting in potatoes Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726567
Reference: Meigh DF, Filmer AAE, Self R, 1973, Growth-inhibitory volatile aromatic compounds produced by *Solanum tuberosum* tubers, Phytochemistry 12: 987-993, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726568
Reference: 1998, 1,4 Sight: An evaluation of sprout suppression on stored potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726569
Reference: 1999, 1,4 Sight: An evaluation of sprout suppression and quality of stored potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726570
Reference: 2000, 1,4 Sight sprout inhibitor: An evaluation of sprout suppression on stored potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1726571
Reference: 2000, 1,4 Sight: An evaluation of sprout inhibition in stored potatoes, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1868600
Reference: 2002, Evaluation of the sprout suppressant capacity of 1,4DMN in common North American potato varieties, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1868602
Reference: 1994, Magnitude of residue of 1,4-dimethylnaphthalene on potato skin and potato pulp after post-harvest fumigation, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1914112
Reference: 2010, Clarification on value of 1,4 Ship, Data Numbering Code: 10.6

PMRA Document Number: 1936479
Reference: 2010, Clarification on use pattern for 1,4 Ship, Data Numbering Code: 10.6

B. Additional Information Considered

1.0 Human and Animal Health

PMRA Document Number: 1917021
Reference: University of California Sustainable Agriculture Research and Education Program, 2004, 1,4-Dimethylnapthalene for use as a post-harvest adjuvant, National Organic Standards Board Technical Advisory Panel review, Data Numbering Code: 6.4, 12.5

PMRA Document Number: 1917025
Reference: New Zealand Food Safety Authority, 2007, Proposals to amend the New Zealand (maximum residue limits of agricultural compounds) food standards 2007: Proposal to exempt 1,4-dimethylnaphthalene, http://www.nzfsa.govt.nz/consultation/mrl/page-15.htm, Data Numbering Code: 6.4

2.0 Environment

PMRA Document Number: 1917021
Reference: University of California Sustainable Agriculture Research and Education Program, 2004, 1,4-Dimethylnapthalene for use as a post-harvest adjuvant, National Organic Standards Board Technical Advisory Panel review, Data Numbering Code: 6.4, 12.5

PMRA Document Number: 1924023
Reference: Phousongphouang PT, Arey J, 2002, Rate constants for the gas-phase reactions of a series of alkylnaphthalenes with the OH radical, Environ Sci Technol 36: 1947-1952, Data Numbering Code: 12.5

PMRA Document Number: 1924124
Reference: Eriksson M, Sodersten E, Yu Z, Dalhammar G, Mohn WW, 2003, Degradation of polycyclic aromatic hydrocarbons at low temperature under aerobic and nitrate-reducing conditions in enrichment cultures from northern soils, App Environ Microbiol 69: 275-284. Data Numbering Code: 12.5

3.0 Value

PMRA Document Number: 1920469
Reference: Forsythe D, Forsythe JM, 2002, Composition and method for reducing odor of substituted naphthalenes, http://www.patentstorm.us/patents/6403536/description.html, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1922783
Reference: Oteef MDY, 2008, Analysis of the potato sprout inhibitor 1,4-dimethylnaphalene: HPLC method development and applications, PhD thesis, University of Glasgow, United Kingdom, Data Numbering Code: 10.6

PMRA Document Number: 1928215
Reference: Agriculture and Agri-Food Canada, 2008, Canada's potato industry, http://www.ats.agr.gc.ca/pro/3639-eng.htm, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1928218
Reference: Statistics Canada, 2010, Area, production and farm value of potatoes (imperial measured), Canada and other provinces, http://www.statcan.gc.ca/pub/22-008-x/2010001/t005-eng.htm, Data Numbering Code: 10.2.3.4

PMRA Document Number: 1929941
Reference: 2010, Feedback from Canadian Horticultural Council Potato Committee regarding value of 1,4-dimethylnaphthalene, Data Numbering Code: 10.2.3.4