Proposed Registration Decision PRD2010-17

3-Methyl-2-Cyclohexen-1-One (MCH Technical)

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Overview

Proposed Registration Decision for 3-Methyl-2-Cyclohexen-1-One (MCH Technical)

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 MCH Technical and MCH Bubble Cap, containing the technical grade active ingredient 3-Methyl-2-Cyclohexen-1-One, to deter Douglas-fir beetle, *Dendroctonus pseudotsugae*, and spruce beetle, *Dendroctonus rufipennis,* from attacking Douglas-fir trees and spruce trees, respectively.

MCH Technical (Registration Number 28638) and MCH Bubble Cap (Registration Number 28637) are conditionally registered in Canada. Although the risks and value of MCH Technical have been found acceptable when all risk-reduction measures are followed, the applicant was required to submit additional scientific information as a condition of registration. The additional information included acute toxicity studies to properly characterize the toxicological hazards of MCH Technical and additional environmental toxicity studies to determine the effect of MCH Bubble Cap on birds. The current applications were submitted to convert MCH Technical and MCH Bubble Cap from conditional registration to full registration. The detailed science review for MCH Technical and MCH Bubble Cap, in addition to the review of data used to fulfill the condition of registration, can be found in the Science Evaluation section of this document.

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 MCH Technical and MCH Bubble Cap.

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

[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."

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 PMRA's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on the application to convert MCH Technical from conditional to full registration, 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 MCH Technical, 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 MCH?

MCH is an anti-aggregation pheromone for both the Douglas-fir beetle and the spruce beetle. This pheromone is released by the beetles after they successfully attack a host tree. When released in sufficient quantities, MCH signals to any incoming beetles that a host tree is already fully occupied thereby deterring additional beetles from attacking the tree because they would not be able to reproduce successfully due to competition from the other beetles already established in the tree. MCH Bubble Cap is applied by stapling individual bubble caps to trees or stumps.

Health Considerations

Can Approved Uses of MCH Affect Human Health?

MCH is unlikely to affect your health when used according to label directions.

Exposure to MCH may occur when handling and applying the product, as well as recovering used and dislodged MCH Bubble Caps. 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

[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*.

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.

Since the technical grade active ingredient, MCH, is slightly acutely toxic in animal studies, the statement, "CAUTION – POISON", has been included on the principal display panel of both the general label and the individual MCH Bubble Cap label, and "Harmful if swallowed" and "Avoid breathing vapours" have been included in the PRECAUTIONS section of the secondary display panel of the general label.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use pattern of MCH Bubble Cap is for non-food situations. Therefore, the use of MCH is not expected to result in dietary risk from food and/or water.

Occupational Risks From Handling MCH

Occupational risks are not of concern when MCH is used according to label directions, which include protective measures.

Pesticide applicators and workers handling and attaching MCH Bubble Caps to Douglas-fir and spruce trees can come in direct contact with MCH on the skin and eyes, if the bubble caps are punctured or improperly sealed. The current label statements adequately mitigate the concern of exposure to the applicators or workers.

Any potential for inhalation of MCH while handling and applying the product is anticipated to be negligible, if the precautionary statements are observed.

Accidental bystander exposure is possible in situations where the bubble cap has been dislodged from the tree and punctured by adults, children, and/or companion animals. Exposure is expected to be negligible, if the precautionary label statement, "Keep out of reach of children and pets", is observed, the bubble cap is properly affixed to the tree, and each individual bubble cap has its own precautionary labelling. Every bubble cap label includes the following information:

> "MCH Bubble Cap
>
> Registration No. XXXXX PCPA
>
> CAUTION POISON [poison symbol]
> EYE AND SKIN IRRITANT
>
> DO NOT puncture bubble caps or handle their contents

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The bubble caps are expected to be depleted of MCH (3-methyl-2-cyclohexen-1-one) within 50 days of application. Removal of the spent bubble caps will not result in any significant post-application exposure to the worker."

Environmental Considerations

What Happens When MCH Is Introduced Into the Environment?

MCH is a highly volatile insoluble anti-aggregation pheromone that is naturally present in the environment at levels higher than the proposed application rate and is not expected to cause any adverse effects to non-target organisms.

MCH is an anti-aggregation pheromone for the Douglas-fir beetle and the spruce beetle. MCH is also a relatively common chemical produced by some animals, found in a variety of food products, and is approved by the FDA as a food additive. MCH bubble caps are slow release plastic pouches containing the active ingredient MCH. MCH bubble caps are attached to standing and fallen Douglas-fir and spruce trees and stumps, and stands containing Douglas-fir or spruce trees. MCH Bubble Cap deters mass attack by the target pests.

MCH is highly volatile and insoluble in water, therefore, it is not expected to leach into ground water or be persistent in water or soil. However, being highly volatile, non-target organisms could be exposed in the air or by direct consumption of the content of the bubble caps. The exposure of non-target terrestrial organisms to MCH under operational conditions is considered to be negligible. MCH is unlikely to bioaccumulate under neutral conditions. MCH has no dissociable moities.

Value Considerations

What Is the Value of MCH Bubble Cap?

MCH, an anti-aggregation pheromone, deters Douglas-fir beetle and spruce beetle from attacking Douglas-fir trees and spruce trees, respectively.

Application of MCH Bubble Cap to Douglas-fir trees and spruce trees deters Douglas-fir beetle and spruce beetle from attacking and killing these trees. Application of MCH Bubble Cap to fallen trees and stumps deters the beetles from infesting these preferred host materials and thereby prevents beetle populations from increasing to levels that threaten healthy trees.

No other pest control products are currently registered for use against either Douglas-fir beetle or spruce beetle to protect trees from attack.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the label of MCH Bubble Cap to address the potential risks are as follows:

Key Risk-Reduction Measures

Human Health

There is a possibility of oral, dermal, and inhalation exposure by workers and bystanders, particularly children and pets, coming into direct contact with dislodged, punctured, or improperly sealed MCH Bubble Caps. Individuals must wash their hands with soap and water after handling, as well as remove any contaminated clothing. Individuals should avoid skin contact and inhalation of the contents of the bubble caps. Children and pets should not be permitted in and around areas where the MCH Bubble Caps have been applied.

Next Steps

Before making a final registration decision on MCH, 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.

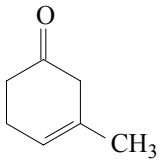
Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on MCH Technical (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

MCH Technical

1.1 Identity of the Active Ingredient

Active substance	3-methyl-2-cyclohexen-1-one
Function	Insect repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-methylcyclohex-2-en-1-one
2. Chemical Abstracts Service (CAS)	3-methyl-2-cyclohexen-1-one
CAS number	1193-18-6
Molecular formula	$C_7H_{10}O$
Molecular weight	110.15
Structural formula	
Purity of the active ingredient	98% nominal (limits: 96.04% - 99.96%)

1.2 Physical and Chemical Properties of the Active Substance and End-use Product

Technical Product - MCH Technical

Property	Result
Colour and physical state	Colourless to yellow
Odour	Nutty odour
Melting range	N/A
Boiling point or range	40°C at 4 mmHg
Density	N/A
Vapour pressure at 25°C	4.2 mmHg

Property	Result
Henry's law constant at 20°C	N/A
Ultraviolet (UV)—visible spectrum	Photostabilizer is added to the technical grade active ingredient during formulation of the end-use product, therefore, the UV-visible absorption spectrum of the additive would affect the absorption of the a.i.
Solubility in water at 20°C	Insoluble in water
Solubility in organic solvents at 20°C (g/100 mL)	Soluble in alcohol
n-Octanol–water partition coefficient (K_{ow})	7
Dissociation constant (pK_a)	The product does not contain any dissociable moiety
Stability (temperature, metal)	Stable under normal conditions

End-use Product - MCH Bubble Cap

Property	Result
Colour	Not required
Odour	Nutty odour
Physical state	Solid
Formulation type	Slow-release generator (SR)
Guarantee	97% nominal (limits: 94.1% - 99.9%)
Container material and description	Plastic slow release (100 dispensers/pack), each 2.2 g dispenser contains 0.4 g of the active ingredient.
Density	N/A
pH of 1% dispersion in water	N/A

Property	Result
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	Study in progress.
Explodability	The product is not explosive.

1.3 Directions for Use

MCH Bubble Cap is an end-use product for application to standing and fallen Douglas-fir and spruce trees and stumps, and forest stands containing Douglas-fir or spruce trees, to deter attack by the Douglas-fir beetle and the spruce beetle. Applications are limited to woodlots, forests, and sawmill yards, and are not to be made in or near areas frequented by small children and pets (e.g., residential lots, parks, camping sites, resorts, and scenic vistas). The product is applied by stapling individual bubble caps to trees or stumps, on the north or shaded side. Bubble caps are placed on trees at a minimum height of 2.5 m above the ground, and only trees greater than 20 cm in diameter require treatment. Application must be made prior to the primary attack flight of the beetles in the spring, and a second application may be needed 50-60 days later. The application rate varies according to characteristics of the specific use site (Table 1.3.1).

Table 1.3.1 Application Rates for MCH Bubble Cap

Use Site	Application Rate
Individual trees	1-2 bubble caps per tree (only trees >20 cm diameter at 2.5 m above ground) plus 1 additional bubble cap per additional 20 cm diameter
Small stands (<1 ha)	1-2 bubble caps per tree on all trees >20 cm diameter at 2.5 m above ground
Large stands (>1 ha)	100-200 bubble caps per hectare, with 1 bubble cap per tree on a grid pattern at 7-10 m spacing
Stumps	1 bubble cap per stump
Windthrown trees	up to 6 bubble caps per tree at 2-3 m spacing along the trunk
Extensive windthrow (>1 ha)	200 bubble caps per hectare on a grid pattern with 7 m spacing

1.4 Mode of Action

MCH is a pheromone; therefore, its mode of action is that it affects the behaviour of the target pest. MCH is produced naturally by Douglas-fir beetle and by spruce beetle once the beetles are established in a host tree. The pheromone serves to prevent too many beetles from attacking the same tree, which would result in reproductive failure due to excessive competition among the beetles for the limited resources within the tree. Because MCH deters the beetles from attacking potential host trees, artificial sources of this pheromone can protect Douglas-fir trees and spruce trees from being attacked and killed by Douglas-fir beetle and spruce beetle, respectively.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Technical Grade of Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in MCH Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The database for MCH (see Appendix I), consists largely of acute data in the available scientific literature and rationales to waive short-term and chronic data/information requirements. The overall scientific quality of the database is considered sufficient to allow characterization of the toxicity and human health risks associated with the technical grade active ingredient, MCH Technical, and end-use product, MCH Bubble Cap, when MCH is used in slow release devices (bubble caps) to deter attack by Douglas-fir beetle and spruce beetle on Douglas-fir trees and spruce trees in forest stands. Additional information contained in the US Department of Agriculture (USDA) Forest Service's report on the human and ecological risks of MCH was also considered. MCH Bubble Cap is registered in the United States by the US Environmental Protection Agency (USEPA) for the same use pattern.

MCH is of slight acute toxicity by the oral route and of low acute toxicity by the inhalation route in Sprague Dawley rats. Clinical signs observed in rats following acute inhalation exposure included decreased activity, suggesting possible depression of the central nervous system which is consistent with low molecular weight ketones and other related compounds. Gross examination of organ tissue from treated animals established no effects that could be attributed to MCH exposure.

MCH is minimally irritating to the eyes in New Zealand white rabbits. Requests to waive acute dermal toxicity, skin irritation, and dermal sensitization studies were accepted based on scientifically valid rationales describing the toxicity of MCH and other structurally-related compounds.

Although acute toxicity and irritation studies on both the technical grade active ingredient and the end-use product are normally required, given that the formulation contains no formulants of toxicological concern, test data only on the technical grade active ingredient was accepted by the PMRA to support the end-use product registration application. Consequently, the end-use product is anticipated to be mildly irritating to the eye.

Acceptable rationales were submitted to waive data requirements for short-term toxicity, prenatal developmental toxicity, mutagenicity and genotoxicity, based largely on the low potential for exposure of individuals to the end-use product when it is applied as directed on the product label.

3.2 Occupational/Bystander Exposure and Risk Assessment

3.2.1 Use Description/Exposure Scenario

MCH is approved as a food additive in the US by the FDA which calculated a threshold for human intake of MCH of 540 mg/person/d. It is estimated that daily per capita dietary intake of MCH is 0.01 and 0.1 mg/person/d in Europe and the US, respectively. Although no metabolism data are available, MCH consumed as a food flavouring agent is presumed to be metabolized to innocuous products.

No dermal absorption data are available for MCH. Under normal use conditions, the possibility of dermal exposure to MCH to workers and the general public is minimal and negligible, respectively. Because the MCH is encased in a plastic matrix (bubble cap) that releases only very small quantities of MCH per unit time, MCH is unlikely to directly contact or contaminate skin of workers and/or the general public. Occupational exposure to MCH is expected to be short-term in duration and predominantly by the dermal route when the end-use product is handled during application. Inhalation of MCH vapour, accidental ingestion, and ocular exposure of the end-use product are also possible if the integrity of the bubble cap material is compromised, but are likely to only be minor routes of exposure.

Each MCH Bubble Cap contains 0.4 g of MCH which comprises about 18% of the end-use product. Caps are designed specifically for slow release of MCH in the environment. At 25 ºC, the average release rate is 7 mg of MCH/Bubble Cap/d, with a maximum of 11 mg for the first day. The estimated lifespan of MCH Bubble Cap in the field is 50–60 days. Each MCH Bubble Cap is manually applied by stapling on trees over 20 cm in diameter at a minimum height of 2.5 m above the ground. A total of 100–200 bubble caps per hectare are recommended, depending on the population density of pest beetles.

Assuming that all of the MCH in a bubble cap is released after a minimum of 50 days and a maximum application rate of 200 bubble caps/ha, the daily average MCH released over a hectare would be 1.6 g of MCH/d. In nature, bark beetles release anti-aggregation pheromones, such as

MCH, when population density reaches a high level. Although no direct measurement of how much MCH released by a beetle has been reported, a similar anti-aggregation pheromone, verbenone, produced by a very closely related species of the mountain pine beetle, *Dendroctonus ponderosae,* has been quantified. A female *D. ponderosae* can produce 0.02766 mg of verbenone/d, while a male of the same species can release 0.03552 mg each day. Based on these release rates, and the number of mass-attacked trees per hectare (176/ha) and number of beetles per tree (786 pairs of beetles/tree), a total of 8.7 g of verbenone/ha/d has been estimated for a typical pest outbreak scenario. By extrapolation to MCH-producing beetles, *D. pseudotsugae* and *D. rufipennis,* release of 8.7 g of MCH/ha/d is estimated in a naturally infested Douglas-fir or spruce forests. The MCH concentration released by MCH bubble caps is estimated to be approximately 5.4 times lower than that of naturally occurring levels from beetle infested forest stands. However, the following two exposure scenarios may be possible: inadvertent dermal contact during placement of MCH Bubble Cap by workers and handling of MCH Bubble Cap by a child.

3.2.2 Occupational

Under typical conditions of placing the MCH Bubble Cap, workers should not be exposed to substantial levels of MCH. The MCH is encased in a plastic matrix that releases only very small quantities of MCH per unit time.

A worst-case exposure scenario for workers would involve accidental dermal contamination of the hands after the bubble cap is removed from its packaging. This scenario postulates that the bubble cap is ruptured in some way during its removal from the packaging material or during its placement on a tree. Based on the assumption that both hands are contaminated with MCH for one minute, estimates of absorbed dose do not exceed 2.1 mg/kg bw. This estimated dose is about 240 times less than the lowest reported lethal oral dose in rats, but is also about 21,000 times greater than the US FDA estimate of daily exposure in food. In a highly implausible exposure scenario, in which the worker does not clean the contaminated hands for one hour, dermal exposure is unlikely to exceed 5.6 mg/kg bw (0.4 g of MCH for each bubble cap and a body weight of 70 kg for the worker). In this case, the dose estimate is limited not by the dermal absorption rate but by the amount of MCH contained in a single bubble cap. This again is well below the lowest reported lethal oral dose in rats (by 89 times), but far above the estimated level of exposure to MCH in foods (by 56,000 times). Therefore, these exposure estimates can conclude that accidental dermal exposure to the entire contents of a single bubble cap is unlikely to be lethal. Due to a lack of short-term and chronic toxicity studies, sublethal effects cannot be discounted from single high-dose or repeated, low-dose exposures to MCH.

The potential for inhalation of MCH while applying the product is anticipated to be negligible if workers observe the precautionary label statements, i.e. “Avoid inhaling fumes; open storage bags outdoors prior to use and allow venting for 10 minutes before removing bubble caps.”

The bubble caps are expected to be depleted of MCH after approximately 50 days of stapling to Douglas-fir and spruce trees. Therefore, the likelihood of exposure to workers during retrieval of the spent bubble caps is expected to be negligible.

3.2.3 Bystander

Under normal conditions, members of the general public could be exposed to trace levels of MCH in the air. In more typical exposure scenarios, bystanders, unlike workers, are likely to walk in and out of a treated area. This transient exposure is not expected to pose a health risk as the concentrations of MCH in air originating from bubble caps will be lower than levels that would occur naturally in forest stands during a beetle infestation.

Accidental exposures, however, are not implausible under operational conditions of use of MCH Bubble Cap. The bubble caps will be attached to trees and may be accessible to young children and companion animals (pets). Even if the bubble caps were to be secured and generally out of reach, a bubble cap could be inadvertently dropped during application or dislodged by wildlife after application and subsequently compromised (punctured or torn). In this scenario, both dermal and oral exposure could occur through handling of the compromised bubble cap. The maximum absorbed dose for the scenario was estimated to be 11.4 mg/kg bw for a 10-year old child weighing 35 kg and 30 mg/kg bw for a 2–3 year-old child weighing 13 kg. The upper limit of 30 mg MCH/kg bw is only about 17-fold less than the minimum lethal dose for rats (i.e., 500 mg/kg bw) which was associated with death in 1 of 10 rats in an acute oral study.

The proximity of an estimated dose for human exposure to the presumed lethal dose in the rat is of concern. No short-term or chronic toxicity data are available to allow identification of potential sublethal effects of MCH. Consequently, the PMRA is unable to discount the potential for adverse effects to occur from maximum exposure scenarios involving children and pets that may accidentally ingest and/or handle a compromised bubble cap.

Since bystanders such as children, adults, and pets could be at risk due to exposure to MCH from a punctured bubble cap, the inclusion of a label on each bubble cap is required, as follows:

> "MCH Bubble Cap
>
> Registration No. XXXXX PCPA
>
> CAUTION POISON [poison symbol]
> EYE AND SKIN IRRITANT
>
> DO NOT puncture bubble caps or handle their contents
>
> Phero Tech International Inc. (604) 940-9944"

These mitigative measures are considered to be adequate to address bystander risk due to exposure. Furthermore, the label-required placement of the bubble caps at a minimum height of 2.5 m above the ground will minimize risk concerns for children and pets.

3.5 Food Residue Exposure Assessment

MCH Bubble Cap is not intended for use on food or feed crops and the active ingredient is wholly contained within a weather-proof capsule. Consequently, the use of MCH is not expected to result in dietary exposures to the public from food and/or water and the PMRA did not need to establish a maximum residue limit (MRL).

4.0 Impact on the Environment

MCH is an anti-aggregation pheromone for the Douglas-fir beetle and spruce beetle. MCH Bubble Caps are attached to standing and fallen Douglas-fir and spruce trees and stumps, and stands containing Douglas-fir or spruce trees. MCH is highly volatile and insoluble in water. As MCH is naturally present in the environment in a gaseous phase, the PMRA assumes that exposure to MCH will be in air upon release. The log K_{ow} indicates the MCH is unlikely to bioaccumulate under neutral conditions. MCH has no dissociable moities.

Approximately 8.7 g of MCH/ha/d is released from a naturally occurring Douglas-fir beetle or spruce beetle infestation. Based on the rate of application of MCH Bubble Cap (200 dispensers/ha) and the release rate of the active ingredient from the bubble caps (11 mg MCH/d), it was estimated that the maximum release rate from the bubble caps would be 2.2 g/ha/d. Terrestrial vertebrates are not expected to consume or tamper with the MCH Bubble Caps. The exposure of non-target organisms to MCH under operational conditions is considered to be negligible. No mitigation measures are required.

4.1 Fate and Behaviour in the Environment

Following the proposed regulatory document PRO2002-02 *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals,* information related to fate and behaviour in the environment was not required and not submitted at this time.

MCH is highly volatile and insoluble in water, therefore it is not expected to leach into ground water or be persistent in water or soil. However, being highly volatile, non-target organisms could be exposed in the air or by direct consumption of the content of the bubble caps.

Studies have shown the maximum release rate from the bubble caps is estimated to be 2.2 g/ha/d. Therefore, the exposure of non-target terrestrial organisms to MCH under operational conditions is considered to be negligible.

4.2 Effects on Non-Target Species

MCH is a pheromone released in the environment in slow-release capsules (i.e. bubble caps) attached to trees. As such, no residues of the active ingredient are expected in the soil, in aquatic systems, on vegetation or other food sources. However, since MCH is released in the environment by volatilization from the bubble caps, the expected environmental concentration in the air of MCH and potential effects on non-target terrestrial invertebrates were considered. Potential exposure to birds and mammals by direct ingestion of MCH Bubble Cap product was also considered.

4.2.1 Effects on Terrestrial Organisms

Invertebrates

The biological activity of MCH is manifested through its dispersal in the atmosphere as a volatile material. Non-target beneficial arthropods could also be exposed to MCH under conditions of field use. Compounds similar in structure to MCH, like various isomers of methylcyclohexanone, are endogenous to cockroaches and may serve as attractant pheromones. In the honey bee, however, methylcyclohexanones appear to act as repellents, which is similar to the effect of MCH on the Douglas-fir beetle.

The activities of methylcyclohexanes, either as attractants or repellents, to other species cannot be directly generalized to the potential effects of MCH on other species. Nonetheless, MCH, 3-methylcyclohexanone, and other structurally similar compounds all act as repellents to the Douglas-fir beetle. Hence, it is plausible that MCH could act as a pheromone in other species, either as an attractant or antiaggregant.

MCH did not appear to adversely impact beneficial arthropods such as the predaceous clerids, *Thanasimus undulates* and *Enoclerus sphegeus*. Naturally occurring Douglas-fir beetle or spruce beetle infestations are estimated to release approximately 8.7 g of MCH/ha/d. The maximum release rate from the bubble caps is estimated to be 2.2 g/ha/d. Therefore, the exposure of non-target beneficial arthropods to MCH under operational conditions is considered to be negligible.

Birds

The acute bobwhite quail and dietary mallard duck LD_{50}s exposed to MCH Technical were 627 mg a.i./kg bw and >1376.3 mg a.i./kg bw/d, respectively. As a condition of initial registration, a scientific rationale, which highlighted field observations showing that birds are not likely to peck, tamper with or eat the bubble caps, was submitted and accepted by the PMRA. Therefore, avian exposure to MCH Technical is not expected to occur in the environment. The use of MCH Bubble cap is considered to pose negligible risks to birds.

Mammals

A potential exposure scenario for terrestrial mammals would involve an animal tampering with the bubble caps and consuming the enclosed liquid MCH. The amount of MCH that would be consumed could range from almost 0 to 390 mg (the amount encased in an individual bubble cap), depending on the amount of time that has elapsed after application.

Assuming that all of the MCH in the MCH Bubble Cap is consumed, and that the sensitivity of wild mammals to MCH is similar to that of the test animals used in the toxicity studies, small wild mammals (i.e., shrews, mice, and rats) could consume doses that exceed a potentially lethal dose (i.e., equivalent to 500 mg/kg for the rat, the LD_{50} for rats was estimated to be between 1000 and 2000 mg/kg bw). Larger mammals, such as raccoons, would be subject to lower doses in terms of mg/kg body weight, as a function of their higher body weights.

Anecdotal evidence, as detailed in the Forest Service submissions to the USEPA regarding several efficacy studies that were conducted on MCH, included MCH Bubble Cap formulations and no incidents of wildlife tampering with the MCH formulations was noted. Furthermore, the apparent efficacy of this compound in these field studies suggests that product loss due to consumption of the formulation by wildlife species is not a common event. Thus, although the likelihood of individual animals consuming the bubble cap or its contents cannot be determined quantitatively, it is unlikely and exposure to wild mammals is considered to be minimal.

Vascular plants

Information regarding toxicity of MCH to terrestrial plants was not available.

4.2.2 Effects on Aquatic Organisms

Given the proposed method of application of MCH Bubble Cap and that MCH is insoluble in water; it is unlikely that aquatic organisms will be exposed to significant levels of MCH. Accidental exposure to aquatic organisms (e.g., a bubble cap dropped into a pond), would not lead to a significant level of exposure. Therefore, the use of MCH Bubble Cap is considered to pose negligible risks to aquatic organisms.

5.0 Value

5.1 Effectiveness Against Pests

A total of eight efficacy trial reports were submitted, one of which provided only anecdotal results and therefore was not reviewed. Of the seven trials reviewed, four were conducted against Douglas-fir beetle in Idaho, Montana, and Oregon between 1972 and 1999, and three were conducted against spruce beetle in Alaska and Montana between 1974 and 1985. All seven trials were reported in peer-reviewed scientific journal articles. The submitted efficacy data demonstrated that MCH can practically eliminate the response of both Douglas-fir beetle and spruce beetle to otherwise attractive baits, and can greatly reduce both attack rates and attack success of the beetles on both standing and fallen trees. In the absence of management options

other than removal and/or destruction of infested host material, the MCH Bubble Cap product is expected to have substantial value in limiting population build-up and destruction of living trees by these pests.

5.1.1 Acceptable Efficacy Claims

The submitted efficacy data support the use of MCH Bubble Cap to protect Douglas-fir trees and spruce trees from attack by Douglas-fir beetle and spruce beetle at application rates of 100-200 bubble caps per hectare on large areas (>1 ha) and up to 6 bubble caps per tree for individual trees. Initial application must be made before the main beetle flight in spring and a second application may be necessary after 50-60 days.

5.2 Phytotoxicity to Host Plants

Phytotoxicity was not assessed but is not expected because the active ingredient is enclosed within a slow-release dispenser (i.e. MCH Bubble Cap) and not applied directly to the host trees.

5.3 Impact on Succeeding Crops

Considering the nature of the product and the long rotation times for forest tree crops, no impact on succeeding crops is expected.

5.4 Economics

No market analysis was provided for this product evaluation; however, there are no other products registered for protection of Douglas-fir or spruce trees from tree-killing bark beetles. Although quantification is difficult, beetle-caused tree mortality is known to have profound adverse ecological and aesthetic effects as well as the serious economic consequences of reduced quantity and quality of timber supply.

5.5 Sustainability

5.5.1 Survey of Alternatives

There are no alternative pest control products registered for use against the Douglas-fir beetle or spruce beetle.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Current management practices for control of Douglas-fir beetle and spruce beetle are limited to removal and/or destruction of infested host material to minimize the potential for an infestation to grow and spread. MCH is well suited to provide a valuable contribution to integrated pest management, being useful not only to protect living trees from attack, but also to prevent beetle population build-up on dead host material to the point where living hosts are threatened. Also, MCH may be used where removal or destruction of host material is impossible or impractical.

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

Development of resistance to pheromone-based pest management strategies in general is considered unlikely, and there is currently no evidence to suggest a mechanism by which resistance to the manipulation of anti-aggregation pheromones could develop.

5.5.4 Contribution to Risk Reduction and Sustainability

MCH represents the only nondestructive pest management tool available for use against Douglas-fir beetle or spruce beetle. It provides a viable option both for limiting pest population build-up and preventing destruction of living trees and stands, thus helping to sustain existing forest ecosystems and resources.

6.0 Pest Control Product 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., CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the review process, MCH Technical 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:

> MCH Technical does not meet Track 1 criteria, and is not considered a Track 1 substance. See Table 5 for comparison with Track 1 criteria.

6.1 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use product 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

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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*.

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:

> MCH Technical and the end-use product, MCH Bubble Cap, 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].

7.0 Summary

7.1 Human Health and Safety

The available toxicological information on MCH is adequate to qualitatively define the toxic effects that may result from human and pet exposure to the active ingredient. Minimal eye irritation and slight acute toxicity were observed in laboratory animals. No other toxicologically significant effects were observed in the available studies for MCH.

Although a margin of exposure could not be estimated based on available toxicological information, it is not expected that exposure to the end-use product, when label instructions and precautions are observed, will result in any significant potential for adverse effects. Workers, and/or bystanders entering treated areas are not expected to be exposed to levels of MCH that will result in unacceptable risk when MCH Bubble Cap is used according to label directions. The precautionary statements on the product labels are adequate to protect workers and bystanders.

Because MCH Bubble Cap is not to be applied to food or feed, the PMRA did not establish a MRL for MCH.

7.2 Environmental Risk

The use of MCH Bubble Cap is not expected to pose a risk to non-target organisms. MCH is naturally present as a pheromone at levels higher than the proposed release rate under operational conditions of use.

7.3 Value

The data submitted in support of registration of the MCH Bubble Cap demonstrate that this product has value in deterring attack by the Douglas-fir beetle and the spruce beetle on their respective hosts.

[8] DIR2006-02, PMRA Formulants Policy.
[9] DIR2006-02, PMRA Formulants Policy.

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 MCH Technical and MCH Bubble Cap, containing the technical grade active ingredient MCH Technical, to deter Douglas-fir beetle and spruce beetle from attaching Douglas-fir trees and spruce trees, respectively.

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

a.i.	active ingredient
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm	centimetre(s)
d	day(s)
FDA	Food and Drug Administration
g	gram(s)
h	hour(s)
ha	hectare(s)
Hg	mercury
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*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)
MAS	maximum average score
MIS	maximum irritation score
MRL	maximum residue limit
N/A	not applicable
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
SR	slow-release generator
TSMP	Toxic Substances Management Policy
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables

Table 1 Acute Toxicity of MCH Technical and Its Associated End-use Product (MCH Bubble Cap)

Study Type	Species	Result	Comment	Reference
Acute Toxicity of MCH Technical				
Oral	Rat – Sprague-Dawley albino	LD_{50} (♂) = 1.3 g/kg (95 % C.I. 0.9-2.3 g/kg bw)	Slight toxicity	1584737
Dermal	A waiver was granted on the basis of available information.			1584738
Inhalation	Rat – Sprague-Dawley albino	LC_{50} > 19.7 mg/L	Low toxicity	1584737
Skin irritation	A waiver was granted on the basis of available information.			1584738
Eye irritation	Rabbit – New Zealand white	MAS[a] = 7.22/110 (24, 48, and 72 h) MIS[b] = 9.33/110 (24 h)	Minimally irritating	1584737
Skin sensitization	A waiver was granted on the basis of available information.			1584738
Acute Toxicity of End-Use Product – MCH Bubble Cap				
Oral	A waiver was granted on the basis of available information.			1304825
Dermal	A waiver was granted on the basis of available information.			1304825
Inhalation	A waiver was granted on the basis of available information.			1304826
Skin irritation	A waiver was granted on the basis of available information.			1304825
Eye irritation	A waiver was granted on the basis of available information.			1304825
Skin sensitization	A waiver was granted on the basis of available information.			1304825

a MAS = maximum average score for 24, 48 and 72 hours

b MIS = maximum irritation score

Table 2 Toxicity Profile of MCH Technical

Study Type	Species	Results[a] (mg/kg/d in M/F)	Reference
90-d dietary	A waiver was granted on the basis of available information.		1304802
30-d dietary	A waiver was granted on the basis of available information.		1304802
Prenatal Developmental toxicity	A waiver was granted on the basis of available information.		1304803
Reverse gene mutation assay	A waiver was granted on the basis of available information.		1304804
Gene mutations in mammalian cells in vitro	A waiver was granted on the basis of available information.		1304804

a Effects observed in males as well as females unless otherwise reported

Table 3 Physical and chemical properties of MCH Technical relevant to the environment

Property	Result	Comment
Vapour pressure at 25°C	4.2 mm Hg	Highly volatile
Henry's law constant at 20°C	N/A	
Ultraviolet (UV) / visible spectrum		Photostabilizer added to MCH during formulation of the end-use product; UV-visible absorption spectra of the additive would affect overall absorption spectra of a.i.
Solubility in water at 20°C	N/A	Insoluble
Solubility (g/L) in organic solvents	N/A	Soluble in alcohol
n-Octanol/water partition coefficient (K_{ow})	56.2 @ pH 7 Log K_{ow} 1.75	Unlikely to bioaccumulate under neutral conditions
Dissociation constant	N/A	Does not contain dissociable moities
Stability	Practically stable under normal conditions	

Table 4 Effects on birds and mammals exposed to MCH Technical

Organism	Exposure	Endpoint value
Birds		
Bobwhite quail	Acute	LD_{50} = 627 mg a.i./kg bw/d
	Dietary	LD_{50}>1376.3 mg a.i./kg bw/d
Mallard duck	Dietary	LD_{50}>1376.3 mg a.i./kg bw/d
Mammals		
Rat	Acute	LD_{50} =1300 mg a.i./kg bw/d

Table 5 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes	N/A
Predominantly anthropogenic[2]	Yes		No – naturally occurring pheromone	N/A
Persistence[3]	Soil	Half-life ≥ 182 days	N/A	N/A
	Water	Half-life ≥ 182 days	N/A	N/A
	Sediment	Half-life ≥ 365 days	N/A	N/A
	Air	Half-life ≥ 2 days or evidence of long range transport	Information not available	N/A
Bioaccumulation[4]	Log K_{OW} ≥ 5		1.75	N/A
	BCF ≥ 5000		Not available	N/A

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Active Ingredient Endpoints	Transformation Products Endpoints
	BAF ≥ 5000	Not available	N/A
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA-toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined, if required (i.e., all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Number	Reference
1304790	2006, DACO 2-chemistry for TGAI, N/A, MRID: N/A, DACO: 2.0, 2.1, 2.12, 2.12.1, 2.12.2, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9
1304791	2006, Manufacturing Methods and Preliminary Analysis for 3-Methyl-2-Cyclohexenone, N/A, MRID: N/A, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4
1304795	1999, Additional properties information on Cyasorb UV-5411, N/A, MRID: N/A, DACO: 2.16
1304796	Patrick Durkin, 2001, Syracuse Environmental Research Associates, Inc., MCH WordPerfect Worksheets for Human Health and Ecological Risk Assessments, N/A, Syracuse Environmental Research Associates, Inc., MRID: N/A, DACO: 2.16
1304823	2006, DACO 3: specifications for EP, N/A, MRID: N/A, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.3.1, 3.4.2, 3.5, 3.5.2, 3.5.4, 3.5.5, 3.5.6
1304824	2006, Appendix A-3: confidential attachment: Manufacturing of the MCH bubble cap, N/A, MRID: N/A, DACO: 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1

2.0 Human and Animal Health

PMRA Number	Reference
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1304803	2006, DACO 4.5.2 and 4.5.3: rat developmental and rabbit developmental studies - waiver request, DACO: 4.5, 4.5.2, 4.5.3
1304804	2006, DACO 4.5.4; 4.5.5 and 4.1.5.6: genotoxicity studies - waiver request, DACO: 4.5, 4.5.4, 4.5.5, 4.5.6
1304805	2006, Joint Expert Committee on Food Additives UN-WHO: Alicyclic ketones, DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.8
1304806	1998, MCH Human Health and Ecological Risk Assessment: Final Report; prepared for USDA Forest Service, DACO: 4.2.1,4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.8, 9.9

1304831 2006, DACO 5: Exposure (occupational and bystander) (EP), DACO: 5.2

1584737 1976, Acute oral toxicity in rats, eye irritation in rabbits, inhalation toxicity in rats, DACO: 4.2.1, 4.2.3, 4.2.4

1584738 2008, Request for data waivers of 3-methyl-2-cyclohexen-1-one (MCH) on dermal toxicity, DACO: 4.2.2, 4.2.5, 4.2.6

3.0 Environment

PMRA Number **Reference**

1304808 2006, 3-Methyl-2-cyclohexene-1-one: a dietary LC_{50} study with the northern bobwhite. Wildlife International, Ltd. Project No. 626-101. Submitted to Phero Tech Inc., Delta, BC. Study Initiation Date July 12, 2006. Study Completion Date September 14, 2006

1304829 1998, MCH Human Health and Ecological Risk Assessment: Final Report; prepared for USDA Forest Service, N/A, MRID: N/A, DACO: 9.6.2.1, 9.6.2.2, 9.6.2.4, 9.6.2.5, 9.6.4, 9.9

1304830 Ross and Daterman, 1994, Reduction of DF beetle infestations in high risk stand by antiaggregation pheromone, N/A, Can. J. For. Res. 24: 2184-2190, MRID: N/A, DACO: 9.9

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1585829 1977, Analysis for dietary LC_{50} determination in quail, 6100079, MRID: N/A, DACO: 9.6.2.1, 9.6.2.2, 9.6.2.4, 9.6.2.5

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1589473 2008, Letter to Alan Vaudry March 31, 2008, N/A, MRID: N/A, DACO: 9.6.4

1589474 2008, Letter to Alan Vaudry April 9, 2008, N/A, MRID: N/A, DACO: 9.6.4

1589475 2008, DACO 9.6.4 Laboratory Studies - Feeding Study (Birds) with End-Use Product - Request for Waiver, N/A, MRID: N/A, DACO: 9.6.4

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1643482 Acute oral toxicity to mallard duck, DACO: 9.6.2.2

4.0 Value

PMRA Number **Reference**

1304836 Ross and Daterman, 1995, Efficacy of an antiaggregation pheromone for reducing Douglas-fir beetle, *Dendroctonus pseudotsugae* Hopkins (Coleoptera: Scolytidae), infestation in high risk stands, The Canadian Entomologist 127: 805-811, MRID: N/A, DACO: 10.6, 9.9

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