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Proposed Re-evaluation Decision

PRVD2017-22

Metam Sodium and Metam Potassium and Their Associated End-use Products

Consultation Document

(publié aussi en français)

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Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Science Evaluation	1
Proposed Regulatory Decision for Metam Sodium and Metam Potassium	2
International Context	3
Next Steps.....	3
Additional Scientific Information.....	3
Science Evaluation.....	5
1.0 Introduction.....	5
2.0 Description of Registered Uses.....	5
3.0 The Technical Grade Active Ingredient.....	6
3.1 Identity	6
3.2 Physical and Chemical Properties	7
4.0 Impact on Human Health	7
4.1 Toxicology Summary	7
4.2 Occupational Exposure and Risk Assessment	8
4.2.1 Soil fumigation.....	8
4.2.2 Sewer Root Control.....	9
4.2.3 Remedial Wood Preservation	10
4.2.4 Industrial Process Fluids	11
4.3 Non-Occupational Exposure and Risk Assessment	12
4.3.1 Bystander Exposure	12
4.3.2 Dietary Exposure and Risk	13
4.3.3 Aggregate Risk Assessment.....	14
4.3.4 Cumulative Assessment	15
5.0 Impact on the Environment.....	15
5.1 Environmental Fate	15
5.2 Environmental Exposure and Risk Assessment	15
5.2.1 Soil Fumigation.....	15
5.2.2 Sewer Root Control.....	16
5.2.3 Remedial Wood Preservation	17
5.2.4 Industrial Process Fluids	17
6.0 Value	17
7.0 Pest Control Product Policy Considerations	18
7.1 Toxic Substances Management Policy Considerations.....	18
7.2 Formulants and Contaminants of Health or Environmental Concern	18
8.0 Incident reports	19
9.0 Conclusions.....	19
List of Abbreviations	21
Appendix I Registered Pest Control Products Containing Metam Sodium or Metam Potassium	23
Table 1 Registered Metam Sodium Products as of 1 September 2017 (excluding discontinued products or products with a submission for discontinuation).....	23
Table 2 Registered Metam Potassium Products as of 1 September 2017 (excluding discontinued products or products with a submission for discontinuation).....	24

Appendix II	Toxicological Reference Doses for Health Risk Assessments.....	27
Table 1	Toxicology reference Doses for Use in Health Risk Assessments of Metam Sodium and Metam Potassium ^a	27
Table 2	Toxicology Reference Doses for Use in Health Risk Assessments of MITC	28
Appendix III	Label Amendments for Products Containing Metam Sodium or Metam Potassium	29
References	33

Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Metam sodium and metam potassium are non-selective pre-plant soil fumigants used to control pathogens including insects, nematodes, bacteria, fungi and weeds in soil. These active ingredients are also used as remedial wood preservatives to treat structural timber (such as poles). In addition, metam sodium is registered for use in sewer lines to control tree roots, and metam potassium is registered for use in water cooling systems and petroleum secondary recovery waters to control microbial activity.

Metam sodium and metam potassium have been re-evaluated based on the health and environmental risk assessments published in the United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED)¹ (2008) and the amended RED² (2009) documents. Additional risk assessments were conducted by the PMRA where deemed necessary and presented in this document.

This document presents the proposed regulatory decision for the re-evaluation of metam sodium and metam potassium including the proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing metam sodium and metam potassium registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Upon application, metam sodium and metam potassium are broken down into several degradates; the primary being methyl isothiocyanate (MITC) which accounts for most of the pesticidal properties. Metam sodium and metam potassium have value as pre-plant soil fumigants and as remedial wood preservatives. Pre-plant soil fumigants are an important tool for the control of soil pests and pathogens in Canada, which can disrupt plant growth and production. When metam sodium or metam potassium is used as a remedial wood preservative, MITC moves rapidly as a gas into treated structural timber and poles to control decay in wood. Metam sodium also has

¹ United States, 2008

² United States, 2009a

value as a root control agent for sewer lines. The intrusion of roots into sewer lines can block or reduce flow, cause overflows, or reduce hydraulic capacity. Finally, metam potassium has value as an antimicrobial agent for control of microbial activity in recirculating water cooling systems and petroleum secondary recovery waters.

Metam sodium and metam potassium are not registered for residential use in Canada. Risk from residential postapplication or bystander exposure to metam sodium, metam potassium or MITC is not of concern under the current conditions of use.

Extensive risk reduction measures were implemented in Canada in 2012 as part of the re-evaluation to minimize exposure to workers and bystanders. However, additional risk-reduction measures and label updates are proposed for all end-use products containing metam sodium or metam potassium to further mitigate risk to workers. Occupational risks are not of concern when products containing metam sodium or metam potassium are used according to the proposed label directions.

Risk from dietary exposure to metam sodium, metam potassium or MITC is not of concern for all registered uses under the current conditions of use.

Overall, metam sodium and metam potassium are unlikely to affect human health when used according to label directions.

With respect to the environment, metam sodium and metam potassium enter the environment when they are applied for soil fumigation. In addition, metam sodium enters the environment when it is applied to sewer lines for root control. Environmental exposure from wood treatment and industrial process fluid uses is expected to be minimal. Metam sodium and metam potassium break down quickly to MITC and are not expected to build-up in soil and water. MITC dissipates quickly in the environment by volatilization followed by photolytic degradation in the atmosphere. MITC is mobile in soil but is not expected to reach ground water due to its volatilization and rapid degradation in soil. Metam sodium, metam potassium and MITC are not expected to accumulate in the tissues of organisms.

Currently registered labels include the risk reduction measures required to minimize potential exposure to non-target organisms. No additional risk reduction measures are proposed. Minor label amendments are proposed to meet current labelling standards.

Overall, when used according to the label directions, metam sodium and metam potassium are not expected to pose risks of concern to the environment.

Proposed Regulatory Decision for Metam Sodium and Metam Potassium

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing metam sodium and metam potassium are acceptable for continued registration for use and sale in Canada, provided that the required risk mitigation measures and label amendments are in place.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of metam sodium and metam potassium, further risk mitigation measures and label updates are being proposed for all end-use products containing metam sodium and metam potassium.

The labels of Canadian end-use product must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

International Context

Metam sodium and metam potassium are currently acceptable for use in other Organisation for Economic Co-operation Development (OECD) member countries, including Australia, the European Union and the United States. As of 24 October 2017, no decisions by any OECD member country to prohibit all uses of metam sodium or metam potassium for health or environmental reasons have been identified.

Next Steps

Before making a final re-evaluation decision on metam sodium and metam potassium, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on metam sodium and metam potassium. The PMRA will then publish a Re-evaluation Decision³ that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Additional Scientific Information

No additional data is required.

³ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Following the re-evaluation announcement for metam sodium and metam potassium, the registrants of the technical grade active ingredients in Canada indicated that they intended to provide continued support for all uses in Canada. The currently registered products containing metam sodium or metam potassium are listed in Appendix I.

The PMRA implemented several risk reduction measures in 2012 to limit user exposure and to further protect the environment (Re-evaluation Notes REV2012-07, *Chloropicrin, Dazomet, Metam Sodium and Metam Potassium Label Improvements for Antimicrobial Products*, REV2012-08, *Chloropicrin, Dazomet, Metam Sodium and Metam Potassium Label Improvements for Soil Fumigant Products* and REV2012-11, *Label Amendments for Soil Fumigant Products Containing Metam Sodium or Metam Potassium*). The measures implemented in 2012 were consistent with measures adopted by the United States Environmental Protection Agency^{4,5} for metam sodium and metam potassium. These measures came into force in Canada in September 2014.

2.0 Description of Registered Uses

Metam sodium and metam potassium are non-selective pre-plant soil fumigants used to control pathogens including insects, nematodes, bacteria, fungi and weeds in soil. Products containing metam sodium or metam potassium are currently registered as soil fumigants for use in greenhouses and outdoors, in soil where food and non-food crops, forest nurseries, seed beds and ornamentals will be planted. Soil fumigants are designated as “Restricted” class products in Canada. The fumigant products are formulated as liquids or emulsifiable concentrates which are applied using ground equipment (for example, soil injection, rotary tiller, fertiliser spreader, chemigation) or hand held equipment (for example, sprinkling can) as a broadcast or row treatment, and incorporated into soil. The soil is sealed and is aerated prior to planting. Metam sodium is also used as a soil fumigant for the prevention of root graft transmission of Dutch Elm disease.

These active ingredients are also used as remedial wood preservatives to treat structural timber (such as poles). The wood preservative end-use products containing metam sodium and metam potassium are formulated as liquids or emulsifiable concentrates. Products are injected into pre-drilled holes in wood, which are then sealed with plugs.

In addition, metam sodium is registered for use in sewer lines to control tree roots. The end-use product is formulated as a solution but is applied as a foam on the inside surface of pipes.

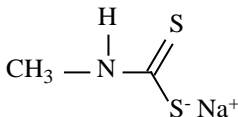
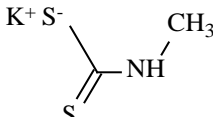
⁴ United States, 2008

⁵ United States, 2009a

Finally, metam potassium is registered as an antimicrobial agent for control of microbial activity in water cooling systems and petroleum secondary recovery waters. The end-use products are formulated as a solution that is added directly to the systems.

3.0 The Technical Grade Active Ingredient

3.1 Identity

	Metam Sodium	Metam Potassium
Common name	Sodium <i>N</i> -methyldithiocarbamate	Potassium <i>N</i> -methyldithiocarbamate
Function	Fungicide, Herbicide, Insecticide, Nematicide, Slimicide	Insecticide, Fungicide, Fumigant, Herbicide, Nematicide
Chemical Family	Dithiocarbamate	Dithiocarbamate
Chemical name		
1 International Union of Pure and Applied Chemistry (IUPAC)	Sodium methyldithiocarbamate	Potassium methyldithiocarbamate
2 Chemical Abstracts Service (CAS)	Sodium <i>N</i> -methylcarbamodithioate	Potassium <i>N</i> -methylcarbamodithioate
CAS Registry Number	137-42-8	137-41-7
Molecular Formula	C ₂ H ₄ NNaS ₂	C ₂ H ₄ NS ₂ K
Structural Formula		
Molecular Weight	129.2	145.29

3.2 Physical and Chemical Properties

Property	Results		
	Metam Sodium		Metam Sodium
Vapour pressure	Non-volatile		Non-volatile
UV-visible spectrum	λ_{\max} (nm)	ε (M ⁻¹ cm ⁻¹)	pH λ_{\max} (nm) Absorbance (A)
	250	9,200	Neutral 248 1.041
	282	11,400	282 1.267
			Alkaline 248 1.023
			282 1.232
			Not stable in acidic media
Solubility in water	7.22×10 ⁴ mg/L		Completely miscible with water
<i>n</i> -Octanol–water partition coefficient	Log <i>K</i> _{ow} <1.0		pH $\log K_{ow}$
			5 -3.42
			7 -3.44
			9 -3.55
Dissociation constant	The sodium salt will completely dissociate		p <i>K</i> _a = 6.87

4.0 Impact on Human Health

Upon application, metam sodium and metam potassium are broken down into several degradates, the primary being methyl isothiocyanate (MITC), which accounts for most of the pesticidal properties. Exposure to parent metam sodium or metam potassium, or the degrade product (MITC), may occur through bystander exposure, while working as a handler or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

4.1 Toxicology Summary

Acute studies conducted in laboratory animals indicated that metam sodium and metam potassium are of low acute toxicity by the oral, dermal and inhalation routes, are not skin or eye irritants, but are dermal sensitizers.

The major degradation product of metam sodium and metam potassium, MITC, is more acutely toxic than the parent compounds. MITC is highly acutely toxic via the oral, inhalation and dermal routes. MITC is also a skin and eye irritant, and a dermal sensitizer.

Based on the high acute toxicity of MITC via the oral, inhalation and dermal routes of exposure and the potential for skin sensitization for metam sodium, metam potassium and MITC, hazard statements are proposed for all product labels (see Appendix III).

The toxicological database for metam sodium, metam potassium and MITC was considered complete for risk assessment purposes.

The toxicological endpoints for metam sodium, metam potassium and MITC used for assessing risk to human health are summarized in Appendix II. A cancer potency factor (q_1^*) has been established for metam sodium and metam potassium and was used to estimate cancer risk.

Based on a review of available information, the databases for metam sodium and metam potassium, and for MITC, contain the full complement of required studies for assessing the potential for developmental toxicity including reproductive studies in rats, and developmental toxicity studies in rats and rabbits. The toxicological endpoints used for risk assessment are expected to be protective of potential effects on the young.

4.2 Occupational Exposure and Risk Assessment

Workers can be exposed to metam sodium, metam potassium or MITC during or after application.

Exposure to parent metam sodium and metam potassium is expected to occur primarily through the dermal route. Due to the volatile nature of MITC, the major route of occupational exposure is expected to be by inhalation.

4.2.1 Soil fumigation

4.2.1.1 Handler Exposure and Risk

Soil fumigant “handlers” are considered any persons involved in the use of the product. This includes: loading/applying the product, perforating/removing tarps, cleaning spills, as well as handling, cleaning, and/or repairing machinery or containers.

Based on the current use pattern (that is, typically one application per year), rapid degradation of the parent compounds to MITC and high volatility of MITC, acute and short-term worker exposures, from the dermal route for metam sodium and metam potassium, and from the inhalation route for MITC, can occur for handlers.

Extensive risk reduction measures were implemented in Canada as part of the re-evaluation to minimize soil fumigant handler exposure to metam sodium, metam potassium and MITC (REV2012-11). These measures include:

- personal protective equipment for all handlers;
- mandatory good agricultural practices (GAPs) to reduce MITC emissions from treated fields, including restrictions regarding site conditions (for example, weather, soil temperature, soil moisture) and practices to be followed during application (for example soil preparation and soil sealing);
- site-specific fumigation management plan (FMP) required for each application which outlines key application requirements;
- mandatory certification or licensing required for all soil fumigant handlers; and
- inclusion of respirator protection and stop work triggers on the label.

Further, the measures require training, detection and response systems to be in place should an accident or spill occur. Together, all of these measures are expected to limit soil fumigant handler exposure to metam sodium, metam potassium and MITC.

Based on the above, the PMRA has determined that the potential risks to handlers from soil fumigant use are not of concern based on the current conditions of use. As noted above (see Section 4.1 for details), hazard statements regarding high acute toxicity and skin sensitization potential are however proposed for all product labels to further protect workers. In addition, to meet the current labelling standards, label statements related to the restricted use of the soil fumigant products are proposed to be updated (see Appendix III for details).

4.2.1.2 Postapplication Exposure and Risk

Because metam sodium and metam potassium rapidly degrade to MITC following application, postapplication exposure to parent metam sodium or metam potassium is not expected to occur. Workers re-entering treated fields or greenhouses after the fumigation to perform activities such as planting, can be exposed to MITC released from treated soil by inhalation. Since metam sodium or metam potassium are typically applied only once per year, occupational postapplication exposure is expected to be of short-term duration.

Extensive risk mitigation measures were implemented in Canada as part of the re-evaluation to minimize the potential for occupational postapplication exposure to MITC (REV2012-11), and are currently included on the product labels:

- mandatory GAPs to reduce emissions from treated fields (see Section 4.2.1.1);
- restrictions pertaining to re-entry into fumigated fields;
- worker notification and posting of fumigation notices on all entrances of the application block prior to and during soil fumigation;
- buffer zone requirements for every fumigant application (see Section 4.3.1.1);
- site-specific fumigation management plan, which covers key steps including:
 - monitoring of site/soil conditions;
 - following the mandatory GAPs;
 - fumigant air monitoring; and emergency response planning.

Together, these measures are expected to limit the potential for occupational postapplication exposure to MITC.

Overall, the PMRA has determined that potential occupational postapplication risks from the use of metam sodium and metam potassium as soil fumigants are not of concern based on the current conditions of use; therefore, no additional risk reduction measures are proposed.

4.2.2 Sewer Root Control

The use of metam sodium in sewers can result in potential dermal exposure to the parent compound and potential inhalation exposure to MITC for handlers. Based on the current use pattern, dermal and inhalation exposures are expected to be of short- to intermediate-term duration in Canada.

As part of the re-evaluation, risk reduction measures were implemented in Canada to further protect handlers from exposure to metam sodium and MITC during applications of metam sodium to sewers (REV2012-07). As such, handler use precautions (pertaining to good hygiene measures and the removal, storage and cleaning of personal protective equipment) are currently included on the end-use product label. In addition, handlers are required to wear coveralls over single-layer clothing, chemical-resistant gloves, chemical-resistant footwear, a chemical-resistant apron, eye protection and a respirator during mixing, loading, transfer, application or any other handling activities. Engineering controls for closed loading and/or transfer systems, and a requirement that the hose be retrieved hydraulically and rinsed off continuously, are also included on the product label. Furthermore, the product label requires ventilation when using the product in confined areas.

The product label currently restricts the sale and use of the end-use product to “*licensed applicators or persons under their direct supervision*”. To further protect workers conversion to “Restricted” classification (that is, “*This product is only to be sold to and used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.*”) is proposed for the end-use product registered for use in sewers.

In addition, to further protect workers, the PMRA is proposing to add respiratory protection and stop work triggers to the label (refer to Appendix III). These measures provide an additional level of protection by requiring respiratory protection (for workers not currently required to wear a respirator), or operations to cease, under certain conditions [for example, if sensory irritation (such as, tearing or burning of the eyes or nose) is experienced or a certain MITC air concentration is reached]. Label amendments are also proposed to require that the personal protective equipment (PPE) currently required for handlers (including a respirator) be available for all support personnel present, and that support personnel must wear this PPE when there is a possibility of exposure to liquid spray or vapours.

Together, all of the above-mentioned mitigation measures are expected to minimize potential exposures and risks to handlers. Thus, under the proposed revised conditions of use, risk to handlers from the use of metam sodium in sewers is not expected to be of concern.

Occupational postapplication exposure to metam sodium or MITC from the use of metam sodium in sewers is expected to be limited since the end-use product is confined to the sewer pipe, and risk is not of concern; therefore, no additional risk mitigation measure is proposed.

4.2.3 Remedial Wood Preservation

For remedial wood treatment of structural timber (such as poles), metam sodium or metam potassium is injected into pre-drilled holes and immediately sealed with plugs. Based on the use pattern, short- to long-term dermal and inhalation handler exposure to metam sodium or metam potassium is expected. Exposure to MITC is not expected for handlers as there is insufficient time for the parent compound to convert to MITC before sealing with plugs.

As part of the re-evaluation, risk reduction measures were implemented in Canada to further protect handlers from exposure to metam sodium or metam potassium during wood treatment (REV2012-07) As such, personal protective equipment (PPE) for handlers (consisting of long

pants, a long-sleeved shirt and chemical-resistant gloves) and Direction for Use statements prohibiting indoor treatment of structures and beams were added to the product labels. In addition, product labels currently include precautionary statements pertaining to acute toxicity, skin and eye irritation, and instructing to avoid inhalation of vapour.

Dermal and inhalation handler exposure to metam sodium or metam potassium was assessed assuming that workers comply with current label protective equipment. Non-cancer risk was not of concern for all exposure scenarios. Cancer risk slightly exceeded the level of concern for the injection application method for workers wearing a single layer of clothing. On this basis, it is proposed that coveralls over single layer clothing be required during mixing, loading, application or all other handling activities (see Appendix III).

Based on the proposed revised use instructions, the risk for workers involved in the treatment of wood with metam sodium or metam potassium is not expected to be of concern.

Exposure to metam sodium, metam potassium or MITC following the treatment of structural timber is expected to be negligible due to the enclosure of the treatment within the pole. On this basis, potential occupational postapplication risk is not expected to be of concern under the current conditions of use. No additional risk reduction measure is proposed.

4.2.4 Industrial Process Fluids

When used in industrial process fluids (that is, recirculating cooling water systems and petroleum secondary recovery waters), metam potassium is added during the industrial process as a solution via open pour or a metering pump. Based on the current use pattern, short- to long-term dermal and inhalation handler exposure to parent metam potassium can occur when the product is being added to the industrial system (for example, loading of the product, connecting/disconnecting a chemical metering pump from a tote). Exposure to MITC during loading is not expected to occur since there will be insufficient time for metam potassium to convert to MITC during handling.

As part of the re-evaluation, risk reduction measures were implemented in Canada to further protect handlers from dermal and inhalation exposures to metam potassium when used for the preservation of industrial process fluids (REV2012-07). As such, handler use precautions (pertaining to good hygiene measures, and the removal, storage and cleaning of personal protective equipment), as well as personal protective equipment for all handlers (consisting of a minimum of a long-sleeved shirt and long pants and chemical-resistant gloves) are currently included on the end-use product labels. Application via a metering pump system is also currently required for products used in water cooling systems.

Based on the above, risk to handlers from the use of metam potassium in recirculating cooling water systems, is not expected to be of concern under current conditions of use. No additional risk reduction measures are proposed for this use.

For the use in petroleum secondary recovery water, the estimated cancer risk for workers wearing current label protective equipment exceeded the PMRA's level of concern ($>1 \times 10^{-5}$). On this basis, additional personal protective equipment (that is, coveralls over single layer clothing) is proposed for petroleum handlers (see Appendix III).

Postapplication inhalation exposure to MITC following the use of metam potassium in petroleum operations is not expected to occur since secondary recovery water is pumped into the oil reservoir in a closed system. Similarly, since recirculating cooling towers are closed systems, and because hot air from water cooling towers is discharged outdoors, occupational postapplication inhalation exposure to MITC from the use of metam potassium in recirculating cooling water towers is expected to be negligible. On this basis, potential occupational postapplication risk is not expected to be of concern under the current conditions of use. No additional risk reduction measure is proposed.

4.3 Non-Occupational Exposure and Risk Assessment

There are no domestic end-use products currently registered for metam sodium or metam potassium. Based on MITC's high volatility, bystander exposure is possible following soil fumigant or wood treatment applications.

4.3.1 Bystander Exposure

4.3.1.1 Soil Fumigation

MITC released from treated soil following application of metam sodium or metam potassium could move off-site to non-target areas and result in bystander exposure.

Extensive risk reduction measures were implemented in Canada to minimize the potential for bystander exposure to MITC following metam sodium or metam potassium soil fumigant applications (REV2012-11). These measures, currently included on the product label, include:

- mandatory GAPs to reduce emissions from treated fields (see Section 4.2.1.1);
- site-specific fumigation management plan (see Section 4.2.1.2), and
- the requirement of a buffer zone for every fumigant application (see below).

Buffer zones provide distance between the application site and bystanders, allowing airborne residues to disperse before reaching bystanders. All non-handlers, including nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone during the Buffer Zone Period (which lasts a minimum of 48 hours after application), except for transit (vehicular and bicycle traffic) through the buffer zone. The size of the required buffer zone is determined by the application rate, field size, application method and credits for use of emission-reduction measures.

Together, all of these measures are expected to limit the potential for bystander exposure to MITC. In consideration of the implemented risk reduction measures, the PMRA has determined that risks to bystanders are not expected to be of concern based on the current conditions of use. No additional mitigation measure is proposed.

4.3.1.2 Remedial Wood Preservation

Mitigation measures were implemented in Canada to minimize the potential for bystander exposure to MITC following metam sodium or metam potassium wood treatment applications, and are currently included on the product label (REV2012-07). As such, the product label includes Direction for Use instructions to ensure that pre-drilled holes are plugged immediately following application, and that MITC is contained within the pole and will not be released into the environment.

Based on the above, the potential for bystander exposure to MITC from its use as a remedial wood preservative is expected to be minimal, and the risk is not expected to be of concern under the current conditions of use. No additional risk reduction measure is proposed.

4.3.2 Dietary Exposure and Risk

4.3.2.1 Exposure from Food

Metam sodium and metam potassium are registered for use as pre-plant soil fumigants on greenhouse and outdoor soil where food or feed crops will be planted. The parent compounds rapidly degrade to MITC upon application. Based on MITC's rapid dissipation in the environment (see Section 5.1) and on the results of available metabolism studies in plants, no residues are expected to be present in food or feed from the registered use for pre-plant soil fumigation.

On this basis, dietary exposure to metam sodium, metam potassium or MITC from food is not expected to be of concern under current conditions of use. No additional risk reduction measure is proposed.

4.3.2.2 Exposure from Drinking Water

4.3.2.2.1 Soil Fumigation

Due to the rapid degradation of metam sodium and metam potassium to MITC in the environment, there is a low potential for the parent compounds to be present in drinking water following soil fumigation applications of metam sodium or metam potassium. Based on MITC's solubility in water and low adsorption in soil, leaching to groundwater and/or transport to surface water may occur. However, under most field conditions, the potential for groundwater and surface water contamination of MITC is expected to be minimal due to its volatilization and fast degradation in soil. MITC was not detected in the available non-targeted groundwater monitoring data. On this basis, risk from the potential exposure to MITC in drinking water is not expected to be of concern under the current conditions of use as a soil fumigant.

To minimize the potential leaching and runoff of MITC, precautionary environmental statements pertaining to the potential for leaching and to conditions that may favor runoff or leaching, and recommended best practices are currently included on the labels of all registered soil fumigant products containing metam sodium or metam potassium. The product label also includes Direction for Use statements related to preventing contamination of aquatic habitats by cleaning of equipment and proper disposal of wastes. No additional risk reduction measures are proposed.

4.3.2.2.2 Sewer Root Control

Due to the rapid degradation of metam sodium to MITC in the environment, there is a low potential for the parent compound to be present in drinking water downstream of treatment facilities. Furthermore, MITC will be volatilized quickly from water following application to sewers.

On this basis, metam sodium and MITC are not expected to contaminate drinking water sources when used for sewer root control under the current conditions of use. No additional risk reduction measures are proposed.

4.3.2.2.3 Remedial Wood Preservation

The potential for ground and surface water contamination from use of metam sodium and metam potassium as a remedial wood preservative is expected to be minimal. Since the end-use product is injected into pre-drilled holes and sealed immediately after, the parent compounds and MITC should be contained within the pole, and release into the environment is expected to be minimal. In addition, the end-use product label contains instructions prohibiting applications to wood that will be used in water.

Based on the above, risk from drinking water exposure to metam sodium, metam potassium and MITC is not expected to be of concern for remedial wood treatment uses. No additional risk reduction measures are proposed.

4.3.2.2.4 Industrial process fluids

Minimal release into the environment (including drinking water sources) is expected from the use of metam potassium in recirculating cooling water systems. The treatment of secondary recovery water is also not expected to result in the contamination of drinking water because terrestrial oil fields typically use berms and catch basins to prevent surface runoff of oil drilling muds and wastes from oil drilling areas, or muds and fluids are recycled. In addition, the label of all metam potassium products registered for use in industrial process fluids currently include a Direction for Use statement prohibiting effluent discharge into the aquatic environment.

On this basis, drinking water contamination from the use of metam potassium in industrial process fluids is expected to be minimal and risk is not expected to be of concern under current use conditions. No additional risk reduction measures are proposed.

4.3.3 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Aggregate exposure from food and drinking water is not expected to be of concern, since the presence of metam sodium, metam potassium or MITC in drinking water is expected to be minimal (see Section 4.3.2). As discussed in Section 4.3.1, there are no domestic-class end-use

products containing metam sodium and metam potassium registered in Canada. Given the limited potential for bystander exposure under current conditions of use (see Section 4.3.1), aggregate exposure is considered to be minimal and risks are not of concern for currently registered uses.

4.3.4 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity.

Given the industrial use pattern of metam sodium/potassium and MITC, and that dietary or residential exposure for metam sodium, metam potassium, and MITC is not expected, there is no requirement for a cumulative risk assessment at this time.

5.0 Impact on the Environment

5.1 Environmental Fate

Metam sodium and metam potassium are non-volatile and readily soluble in water. Metam sodium and metam potassium are subject to hydrolysis, and photolysis in soil and water. In terrestrial and aquatic environments, metam sodium and metam potassium very rapidly degrade to MITC.

MITC is highly soluble in water and has low adsorption in soil. MITC is subject to hydrolysis, and to photolysis in air and water. Based on its high vapor pressure and Henry's law constant, MITC is expected to rapidly volatilize from fields treated with metam sodium or metam potassium and from water.

Based on the octanol/water partition coefficients for metam sodium, metam potassium, and MITC, bioaccumulation of these chemicals is unlikely.

The dissipation of MITC appears to be predominantly dependent on volatilization followed by photolytic degradation in the atmosphere. MITC has potential for leaching to groundwater based its high solubility in water and low adsorption to soil. However, groundwater contamination by MITC is considered unlikely due to its volatilization and rapid degradation in soil. MITC can also potentially move to surface water through runoff. However, it is expected to volatilize rapidly from surface water.

5.2 Environmental Exposure and Risk Assessment

Because of the rapid conversion of metam sodium to MITC, the focus of the environmental exposure and risk assessment is primarily MITC.

5.2.1 Soil Fumigation

Based on the Canadian use pattern (that is, typically one application per year, during a very narrow application window) and MITC's rapid dissipation in the environment, the focus of the risk assessment was acute exposure to MITC.

Extensive mitigation measures were implemented as part of the re-evaluation in 2012 for soil fumigant products containing metam sodium or metam potassium to further protect human health and the environment (REV2012-11). The implemented risk reduction measures will reduce ecological risks by providing an incentive to reduce fumigant application rates and individual treatment areas. Further, the risk reduction measures aimed at minimizing the release of MITC from treated fields (for example, mandatory good agricultural practices (GAPs), see Section 4.2.1.1) will mitigate potential environmental exposure.

In addition, precautionary environmental statements pertaining to toxicity to aquatic organisms, best practices to reduce runoff and leaching, as well as measures to mitigate contamination of aquatic habitats (for example, mandatory GAPs related to tarp perforation and removal) are currently included on the label of the end-use products registered for use as a soil fumigant. The product labels also include precautionary statements related to preventing contamination of aquatic habitats by cleaning of equipment and proper disposal of wastes.

The implemented mitigation measures are expected to mitigate potential risk to non-target organisms. No further risk reduction measures beyond those currently on the product labels are proposed. Minor label updates are proposed to meet current labelling requirements (see Appendix III).

5.2.2 Sewer Root Control

MITC is expected to volatilize quickly from water and is not expected to persist in the aquatic environment.

Several conditions of use are currently included on the product label to minimize the potential exposure of aquatic systems to MITC and reduce potential risk. Sewer applications are limited to systems where the waste water is treated before release to the environment. Applicators must also notify the sewage treatment plant prior to application so that the biological breakdown process in the plant can be monitored during the application. If any adverse effects are noted within the sewage treatment plant, the application must cease. Applications where insufficient dilution is possible (for example, close proximity to the sewage plant or applications conducted at night), are also required to use reduced application rates. Furthermore, consistent with current practices, the product label includes precautionary statements related to preventing contamination of water.

Terrestrial plants could be exposed to MITC in case of spillage near growing plants. The product label currently includes a statement instructing users not to spill or discard solution waste within one-meter of the drip-line of plants, shrubs or trees, and not to flush excessive spillage near growing plants with water.

Overall, based on current use conditions, environmental exposure to MITC from the use of metam sodium in sewers is not expected to be of concern. No additional risk reduction measures are proposed. Minor label updates are proposed to meet current labelling requirements (see Appendix III).

5.2.3 Remedial Wood Preservation

The potential for environmental exposure from the use of metam sodium or metam potassium for remedial wood preservation is expected to be minimal. Since the end-use product is injected into pre-drilled holes and immediately sealed, the parent compounds and MITC should be contained within the pole, and release into the environment is expected to be minimal. In addition, the end-use product label contains instructions prohibiting applications to wood that will be used in water.

Under current conditions of use, risk from potential environmental exposure as a result of the use of metam sodium or metam potassium for remedial wood preservation is not expected to be of concern. No additional risk reduction measures are proposed. Minor label amendments are proposed to meet current labelling requirements (see Appendix III).

5.2.4 Industrial Process Fluids

Based on the use pattern (that is, indoor use and recirculating systems), environmental exposure to metam potassium or MITC from the use of metam potassium in recirculating cooling water systems is expected to be negligible.

Environmental exposure resulting from use in oilfield production (including the treatment of secondary recovery water) is considered to pose limited risk to non-target organisms based on the use of berms and catch basins to prevent surface runoff of oil drilling muds and wastes from oil drilling areas, and fluids are recycled. Estuarine and marine aquatic organisms may be temporarily exposed during marine drilling; however, impacts are expected to be limited to a defined area around the oil well.

The label of all metam potassium products registered for use in industrial process fluids currently include advisory label statements pertaining to the toxicity to aquatic organisms and Direction for Use statements prohibiting effluent discharge into aquatic environments.

Based on the above, risk to non-target organisms is not expected to be of concern for the use of metam potassium in industrial process fluids under current conditions of use. No additional risk reduction measures are proposed.

To meet current labelling standards, it is proposed that additional precautionary statements pertaining to preventing contamination of water by cleaning equipment, proper disposal of waste, and appropriate storage of the product, be added to products labels. An updated Direction for Use statement pertaining to effluent discharge is also proposed (see Appendix III).

6.0 Value

Metam sodium and metam potassium have value as pre-plant soil fumigants and as remedial wood preservatives. Pre-plant soil fumigants are an important tool for the control of soil pests and pathogens in Canada such as insects, nematodes, bacteria, fungi and weeds, which can disrupt plant growth and production. When metam sodium or metam potassium is used as a fumigant remedial wood preservative, MITC moves rapidly as a gas into treated structural timber and poles to control decay in wood.

Metam sodium also has value as a root control agent for sewer lines. The intrusion of roots into sewer lines can block or reduce flow, cause overflows, or reduce hydraulic capacity. Finally, metam potassium has value as an antimicrobial agent for control of microbial activity in recirculating water cooling systems and petroleum secondary recovery waters.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03,⁶ the assessment of metam sodium and metam potassium and its transformation products against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. The PMRA has reached the conclusions that:

- The half-lives of metam sodium⁷ in soil, water and sediment are below the Track 1 criteria for these media. The half-lives of MITC in air, soil, water and sediment are also below the Track 1 criteria for these media.
- The octanol-water partition coefficients for metam sodium and MITC are below the Track 1 criterion.

Based on the above analysis, metam sodium, metam potassium and MITC do not meet Track 1 criteria, and are not considered Track 1 substances.

7.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical are compared against the list in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01⁸ and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,⁹ 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:

- Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

⁶ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

⁷ The TSMP assessment was conducted for metam sodium based on environmental fate values reported in the USEPA RED. Since metam sodium and metam potassium have virtually identical physical chemical properties, the assessment of metam sodium is considered to be applicable to metam potassium.

⁸ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the *New Pest Control Products Act*.

⁹ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

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

8.0 Incident reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. The incident report data were incorporated into the re-evaluation of metam sodium and metam potassium.

As of 28 July 2017, one moderate human incident report was received for metam sodium. An individual was working with the product for 12 hours, and for the last 6 of those hours, his gloves were wet from rain and soaked with the product. He developed blisters and sought medical treatment. There was no indication that the subject was wearing chemical resistant gloves, which are a requirement on the product label. One packaging failure incident was received by the PMRA. In that incident, 250 gallons of metam sodium spilled onto the road from a nurse tank being hauled by a grower. No human exposure or effects related to environmental exposure were reported in this incident. No human incidents have been reported for metam potassium.

As of 28 July 2017, one environmental incident report involving metam sodium had been submitted to the PMRA. Metam sodium was one of a number of chemicals stored at a distribution warehouse. The water used to douse the fire entered a local creek resulting in the death of a large number of fish. Although the role of metam sodium cannot be ruled out, it was considered unlikely to have been the main contributing factor in the fish deaths.

The USEPA's Ecological Incident Information System (EIIS) was queried for environmental metam sodium and metam potassium incidents that were available in the database (version of 5 October 2015). There were 13 incident reports available in the EIIS database classified as being at least possibly related to the reported exposure to metam sodium; no incidents were reported for metam potassium. Six aquatic incidents were reported. One involved the death of 2700 bass fish following drift from an agricultural area, while another involved the death of 1000 fish, including trout, sucker, squawfish, and sculpin, following a spill of metam sodium from a railcar. The remaining aquatic cases resulted in the death of unknown numbers of fish. Plant damage was also reported in seven cases, either through direct treatment (three cases, potatoes and peanuts) or from drift (four cases, conifer, apple, spruce, pine, and cherry trees).

Based on the current and proposed mitigation measures, no additional mitigation is proposed based on the incident report review.

9.0 Conclusions

Upon application, metam sodium and metam potassium are broken down into several degradates; the primary being methyl isothiocyanate (MITC) which accounts for most of the pesticidal properties. Metam sodium and metam potassium have value as pre-plant soil fumigants and as remedial wood preservatives. Metam sodium also has value as a root control agent for sewer lines, while metam potassium has value as an antimicrobial agent for control of microbial activity in recirculating water cooling systems and petroleum secondary recovery waters.

Metam sodium and metam potassium are not registered for residential use in Canada. Risk from residential postapplication or bystander exposure to metam sodium, metam potassium or MITC is not of concern under the current conditions of use.

Occupational risks are not of concern when products containing metam sodium or metam potassium are used according to the proposed label directions, which include protective measures.

Risk from dietary exposure to metam sodium, metam potassium or MITC is not of concern for all registered uses under the current conditions of use.

Overall, metam sodium and metam potassium are unlikely to affect human health when used according to label directions.

With respect to the environment, metam sodium and metam potassium enter the environment when they are applied for soil fumigation. Metam sodium also enters the environment when it is applied to sewer lines for root control. Environmental exposure from wood treatment and industrial process fluid uses is expected to be minimal. Metam sodium and metam potassium break down quickly to MITC and are not expected to build-up in soil and water. MITC dissipates quickly in the environment by volatilization followed by photolytic degradation in the atmosphere. MITC is mobile in soil but is not expected to reach ground water due to its volatilization and rapid degradation in soil. Metam sodium, metam potassium and MITC are not expected to accumulate in the tissues of organisms.

Currently registered labels include the risk reduction measures required to minimize potential exposure to non-target organisms. No additional risk reduction measures are proposed. Minor label amendments are proposed to meet current labelling standards.

Overall, when used according to the label directions, metam sodium and metam potassium are not expected to pose risks of concern to the environment.

List of Abbreviations

amu	atomic mass unit
bw	body weight
EEC	expected environmental concentration [also estimated environmental concentration]
EEIS	Ecological Incident Information System
g	gram(s)
GAP	good agricultural practice
Kg	kilogram(s)
K_{ow}	<i>n</i> -octanol–water partition coefficient
L	litre
LOAEL	lowest observed adverse effect level
LOC	level of concern
mg	milligram
MITC	methyl isothiocyanate
MOE	margin of exposure
nm	nanometre
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
pH	-log ₁₀ hydrogen ion concentration
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Pest Control Products Containing Metam Sodium or Metam Potassium

Table 1 Registered Metam Sodium Products as of 1 September 2017 (excluding discontinued products or products with a submission for discontinuation)

Registration Number	Marketing Class	Registrant	Product Name	Registered Use Type	Formulation Type	Guarantee
18627	Technical	Buckman Laboratories of Canada, Ltd.	SNMDC (33%) Liquid Microbicide Concentrate	-	Solution	33.0%
19399	Technical	Amvac Chemical Corporation	Vapam Technical	-	Solution	44%
24327	Technical	Buckman Laboratories of Canada, Ltd.	SNMDC Concentrate Liquid Microbicide	-	Solution	42%
28170	Technical	Taminco US LLC.	Metam Sodium Technical Formula	-	Solution	42%
28323	Manufacturing concentrate	Taminco US LLC.	Metam Sodium MUP Formula	-	Solution	41.98%
6453	Restricted	Amvac Chemical Corporation	Vapam Liquid Solution Soil Fumigant	Pre-Plant Soil Fumigant	Solution	380 g/L
19421	Restricted	Buckman Laboratories of Canada, Ltd.	Busan 1020	Pre-Plant Soil Fumigant	Solution	33%
25103	Restricted	Buckman Laboratories of Canada, Ltd.	Busan 1236	Pre-Plant Soil Fumigant	Solution	42%
28247	Restricted	Taminco US LLC.	Metam Sodium Agricultural	Pre-Plant Soil Fumigant and Wood Treatment	Emulsifiable Concentrate or Emulsion	380 g/L
29128	Restricted	Amvac Chemical Corporation	Vapam HL	Pre-Plant Soil Fumigant	Liquid	42%
29142	Restricted	Taminco US LLC.	Engage Agro Enfuse M 510	Pre-Plant Soil Fumigant and Wood Treatment	Solution	41.98%
13139	Commercial	Amvac Chemical Corporation	Pole-Fume	Wood Treatment	Solution	380 g/L
17110	Commercial	North Star Structural Contractors Ltd.	Woodfume	Wood Treatment	Liquid	380 g/L
25000	Commercial	Buckman Laboratories of Canada, Ltd.	Busan 1020W	Wood Treatment	Solution	33%
29770	Commercial	Amvac Chemical Corporation	Pole Fume HL	Wood Treatment	Liquid	42%

Registration Number	Marketing Class	Registrant	Product Name	Registered Use Type	Formulation Type	Guarantee
30015	Commercial	Univar Canada Ltd.	Guardsman Post & Pole Fumigant 42%	Wood Treatment	Liquid	42%
30225	Commercial	Douglas Products and Packaging Company, LLC.	Sanafoam B (A Component of the Sanafoam® Vaporooter® II Tank Mix Concept)	Sewer Line Root Control	Solution	30%

Table 2 Registered Metam Potassium Products as of 1 September 2017 (excluding discontinued products or products with a submission for discontinuation)

Registration Number	Marketing Class	Registrant	Product Name	Registered Use Type	Formulation Type	Guarantee (%)
18592	Technical	Buckman Laboratories of Canada, Ltd.	PNMDC (54%) Liquid Microbicide Concentrate	-	Solution	KMC: 54
30180	Technical	Taminco US LLC.	Taminco Metam K Technical	-	Liquid	KMC: 54.1
18931	Manufacturing concentrate	Buckman Laboratories of Canada, Ltd.	Nabe-M Liquid Microbicide	-	Solution	KMC: 20.3 DCD: 14.7
30236	Manufacturing concentrate	Taminco US LLC.	Taminco Metam K MUP	-	Solution	KMC: 54.0
25124	Restricted	Buckman Laboratories of Canada, Ltd.	Busan 1180	Pre-Plant Soil Fumigant	Solution	KMC: 54
30237	Restricted	Taminco US LLC.	Enfuse K 690	Pre-Plant Soil Fumigant and Wood Treatment	Solution	KMC: 54
20935	Commercial	Buckman Laboratories of Canada, Ltd.	DK-17.5 Liquid Microbicide	Water Cooling System and Petroleum Industries	Solution	KMC: 10.15 DCD: 7.35
20936	Commercial	Buckman Laboratories of Canada, Ltd.	DK-11.7 Liquid Microbicide	Water Cooling System and Petroleum Industries	Solution	KMC: 6.8 DCD: 4.9
20937	Commercial	Buckman Laboratories of Canada, Ltd.	DK-8.75 Liquid Microbicide	Water Cooling System and Petroleum Industries	Solution	KMC: 5.07 DCD: 3.68
21689	Commercial	Controlchem Canada Ltd.	Controlchem 2602 – Liquid Microbicide	Cooling Water System	Solution	KMC: 5.07 DCD: 3.68
23355	Commercial	Enercon Water Treatment Ltd.	EC-630 Liquid Microbicide	Cooling Water System	Solution	KMC: 6.8 DCD: 4.9

Registration Number	Marketing Class	Registrant	Product Name	Registered Use Type	Formulation Type	Guarantee (%)
23830	Commercial	Buckman Laboratories of Canada, Ltd.	DK-14 Liquid Microbicide	Water Cooling System and Petroleum Industries	Solution	KMC: 8.12 DCD: 5.88
24038	Commercial	Buckman Laboratories of Canada, Ltd.	Bulab 6003 Liquid Microbicide	Water Cooling System and Petroleum Industries	Solution	KMC: 8.12 DCD: 5.88

KMC = Sodium potassium; DCB = Dichlobenil

Appendix II Toxicological Reference Doses for Health Risk Assessments

Table 1 Toxicology reference Doses for Use in Health Risk Assessments of Metam Sodium and Metam Potassium ^a

Exposure Scenario	Dose ^b (mg/kg bw/day)	Study	UF ^c
Acute Dietary	Acute dietary endpoints were not selected since the use pattern does not indicate potential for dietary exposure.		
Chronic Dietary	Chronic dietary endpoints were not selected since the use pattern does not indicate potential for dietary exposure.		
Short-term dermal (1-30 days)	Maternal (oral) NOAEL = 4.22	Developmental toxicity in rats LOAEL=16.88 mg/kg bw/day, based on reduced body weight gain and decreased food efficiency in maternal rats	Occupational LOC for MOE = 100 ^d
Intermediate-term dermal (1-6 months)	Oral NOAEL = 0.1	Chronic toxicity in dogs LOAEL = 1 mg/kg/day, based on increased ALT and microscopic changes in the liver in females	Occupational LOC for MOE = 100 ^d
Long-term dermal (>6 months)	Oral NOAEL = 0.1	Chronic toxicity in dogs LOAEL = 1 mg/kg/day, based on increased ALT and microscopic changes in the liver in females	Occupational LOC for MOE = 100 ^d
Dermal Absorption	2.5% based on the in vivo rat study		
Short-, intermediate- and long-term inhalation (1 day to >6 months)	NOAEL = 6.5 mg/m ³ (1.11 mg/kg/day)	90-day inhalation study LOAEL = 7.71 mg/kg/day, based on histopathological changes in the nasal passages (that is, mucigenic hyperplasia) and changes in clinical chemistry	HEC: 6.5 mg/m ³ (1.11 mg/kg/day) UF = 100 ^d
Cancer (oral, dermal, inhalation)	Classification: Probable human carcinogen (B2) q1* = 1.98×10^{-1} in human equivalents converted from animals		

^a From United States 2004b and 2009b.

^b NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level

^c LOC = Level of concern; MOE = Margin of exposure; UF = uncertainty factor; HEC = human equivalent concentration

^d 10-fold uncertainty factor for interspecies extrapolation, 10-fold uncertainty factor for intraspecies variations

Table 2 Toxicology Reference Doses for Use in Health Risk Assessments of MITC

Exposure Scenario	Dose ^a (mg/kg bw/day)	Study	UF ^b
Dermal (all durations)	Dermal endpoints have not been selected as a quantitative assessment was not conducted-		
Acute Inhalation ^c	1 min NOAEL = 3.3 ppm 4-14 min NOAEL = 0.6 ppm 1-8 hr NOAEL = 0.22 ppm	Eye irritation study Based on subjective responses to the Likert scale and eyeblink responses	1 min HC = 3.3 ppm UF = 10 ^d 4-14 min HC = 0.6 ppm UF = 10 ^d 1-8 hr HC = 0.22 ppm UF = 10 ^d
Short- term inhalation (1-30 days) ^c	NOAEL = 6.8 ppm	28-day inhalation study in rat LOAEL = 34 ppm, based on metaplasia of respiratory epithelium and atrophy of the olfactory epithelium	Non-occupational HEC = 0.16 ppm ^e UF = 30 ^f Occupational HEC = 0.68 ppm ^e UF = 30 ^f
Intermediate-to long-term inhalation ^g (>30 days)	NOAEL = 0.5 ppm	Combined chronic toxicity/carcinogenicity study in rat LOAEL = 5 ppm, based on effects on the respiratory tract	Occupational HEC = 0.10 ppm UF = 100 ^h
Cancer ^g (oral, dermal, inhalation)	Nasal squamous cell carcinomas occurred at a dose that exceeded the MTD in rats and therefore, were not considered relevant for risk assessment purposes		

^a NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level

^b UF = uncertainty factor; HEC = Human equivalent concentration; HC = Human concentration

^c From United States 2004b and 2009b.

^d UF = 10-fold for intraspecies variability. An interspecies factor was not added since the endpoint is based on a human study.

^e HECs differ between non-occupational and occupational scenarios because the residential HEC is based on 24-hour exposures occurring 7 days per week, whereas the occupational HEC is based on 8-hour exposures occurring 5 days per week.

^f UFs = 10-fold for intraspecies variability; 3-fold for interspecies extrapolation (based on PK differences between rats and humans)

^g Based on information submitted to the PMRA through the Incident Reporting Program.

^h UFs = 10-fold for intraspecies variability; 10-fold for interspecies extrapolation

Appendix III Label Amendments for Products Containing Metam Sodium or Metam Potassium

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products registered in Canada must be amended to include the following statements to further protect human health and the environment.

- I) For technical grade, manufacturing concentrates and end-use products containing metam sodium or metam potassium, the following key signal words must be included on the primary panel of the label:

DANGER POISON
DANGER – CORROSIVE TO EYES
DANGER SKIN IRRITANT
POTENTIAL SKIN SENSITIZER

- II) In the **NATURE OF RESTRICTION** section of the primary display panel of the end-use products registered for soil fumigation, the following statement must be removed:

This product is only to be used by individuals holding an appropriate pesticide applicator certificate or license recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur. This restriction applies to all fumigant handlers, as defined in the **HANDLER RESTRICTIONS** section of this label.

and replaced with:

This product is only to be sold to and used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur. This restriction applies to all fumigant handlers, as defined in the **HANDLER RESTRICTIONS** section of this label.

- III) On the primary display panel of the end-use product registered for sewer root control, the following statement must be removed:

For retail sale to and use only by licensed applicators or persons under their direct supervision and only for those uses covered by the licensed applicator's certification.

and replaced with:

RESTRICTED PRODUCT

The following statements must be included in a section entitled **NATURE OF RESTRICTION:**

This product is only to be sold to and used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.

- IV) The following statement must be included in a section entitled **PRECAUTIONS.**

For all end-use products:

Fatal or Poisonous if swallowed or absorbed through the skin. DO NOT get on skin or on clothing. Harmful if inhaled. Avoid inhaling/breathing vapour or sprays. CORROSIVE to the eye and to skin. DO NOT get in eyes or on skin. Potential skin sensitizer.

For end-use products registered for wood preservation or preservation of petroleum secondary recovery water:

Wear coveralls over a long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, and protective eyewear during mixing, loading, application and all other handling activities.

- V) For the end-use product registered for sewer root control, the following statements under **PRECAUTIONS** must be removed:

Personal Protective Equipment:

Wear coveralls over a long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron (if transferring or loading the product or cleaning up spills or equipment), and a respirator during mixing, loading, transfer, application or any other handling activities. The respirator must be a NIOSH-approved half-face, full-face, or helmet/hood style respirator with either, an organic-vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G). In addition, wear face-sealing goggles if using a half-face respirator.

All support personnel who remain outside the treatment zone and who are not exposed to either liquid spray or vapours must wear a long-sleeved shirt, long pants, and shoes plus socks. In addition, when they may be exposed to liquid spray or vapours, they must have immediately available, and must wear in an emergency, the handler PPE listed above in this section.

and replaced with:

Personal Protective Equipment:

Wear coveralls over a long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron (if transferring or loading the product or cleaning up spills or equipment), and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides during mixing, loading, transfer, application or any other handling activities. In addition, wear face-sealing goggles if using a half-face respirator.

Support personnel must wear a long-sleeved shirt, long pants and shoes plus socks. In addition, they must have the handler PPE listed above in this section immediately available, and must wear it, when there is a possibility of exposure to either liquid spray or vapours.

The following statements must also be included under **PRECAUTIONS** (after the **Engineering Controls for Closed Loading and/or Transfer Systems** Section):

Respiratory Protection and Stop Work Triggers:

All handlers must wear a respirator during all mixing, loading, transfer, application or any other handling activities (see **Personal Protective Equipment** Section). Support personnel are not required to wear a respirator, but must have a respirator immediately available in the event of an emergency. The procedures outlined in Table X must be followed to determine if operations must cease.

Table X Respiratory Protection and Stop Work Triggers

If at any time any person experiences sensory irritation <u>when not wearing a respirator</u>	Then either: <ul style="list-style-type: none"> Operations must cease and all personnel present must leave the site. OR <ul style="list-style-type: none"> An air-purifying respirator must be worn by all personnel and air monitoring samples must be collected for MITC every 2 hours at the location where irritation was first experienced.
If at any time any person experience sensory irritation <u>when wearing a respirator</u>	Operations must cease and all personnel must leave the site.
If at any time a MITC air sample is greater than or equal to 6 ppm	Operations must cease and all personnel must leave the site.
If operations must cease, work can only resume provided:	<ul style="list-style-type: none"> All personnel wear a respirator, Two consecutive breathing zone samples for MITC taken at least 15 minutes apart are less than 6 ppm at the location where irritation was first experienced, Handlers do not experience sensory irritation while wearing a respirator,

	<ul style="list-style-type: none">• Respirator cartridges/canisters have been changed, and• Air monitoring samples must be collected at least every 2 hours in the breathing zone of a handler.
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VI) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

For end-use products registered for wood preservation or preservation of industrial process fluids:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

For end-use products registered for sewer root controls and industrial process fluids:

DO NOT discharge effluent containing this product or the biocide produced into lakes, streams, ponds, estuaries, oceans or other waters unless the effluent has been detoxified by suitable means.

For end-use products registered for soil fumigation in greenhouses:

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

VII) The following statements must be included in a section entitled **STORAGE**.

For all end-use products:

To prevent contamination store this product away from food or feed.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY THE REGISTRANT

PMRA Document Number	Reference
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1738327	1996, [CBI Removed] Specifications and Analytical Methodology required for registration of the technical active ingredient: SNMDC Concentrate. Process modification to reduce pH and add colorant. Confidential Appendix and Attachments I and II., DACO: 2.1,2.10,2.12,2.13,2.14.6,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1738333	[CBI Removed] - Response to Chemistry Review on SNMDC, PNMD C Active Ingredient Samples, PNMD C [CBI Removed] Standard and Validation, Quality Control Data from the Five Batches of SNMDC Concentrate. Determination of Storage Stability and Corrosion Characteristics of Metam Concentrate, [CBI Removed], SNMDC Data Package., DACO: 2.99
1738638	1994, [CBI Removed] - Specifications and Analytical Methodology Required for Registration of the Technical Active Ingredient, SNMDC Concentrate. Attachment I Metam Concentrate - Physical and Chemical Characteristics, Attachment II - Determination of Stability of Metam Concentrate Under Accelerated Storage Conditions. Volume 2 Attachment I - Manufacturing Process for Metam Concentrate, Attachment II - Product Chemistry for Metam Concentrate, Attachment III - Official Testing Standard Used for Quality Control "Spectrophotometric Analysis of Dithiocarbamates"., DACO: 2.1,2.10,2.11,2.13,2.14.1,2.14.10,2.14.11,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
1840009	1990, [CBI Removed] Metam-Sodium - Dissociation Constant, Stability, and Oxidizing/Reducing Action, DACO: 2.14.13
1840169	1985, [CBI Removed] Physical and Chemical Properties of Metam-Sodium, DACO: 2.14
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2676350	2007, Metam Sodium - Manufacturing Process, DACO: 2.11.1,2.11.2,2.11.3 CBI
2684692	2016, Manufacturing Method for Y apam Technical, DACO: 2.11 CBI
2686585	2016, Manufacturing Method for Vapam Technical, DACO: 2.11 CBI
2772540	2017, Memorandum, DACO: 2.13.4 CBI
1643891	1996, Technical Chemistry [CBI Removed]. Confidential Appendix to Part 2. Specifications and Analytical Methodology Updated Product Chemistry: PNMD C. Attachments I, II, III., DACO: 2.99
1643987	1998, Technical Chemistry [CBI Removed].PNMD C Response to Chemistry Review., DACO: 2.99

1643989	1983, Technical Chemistry [CBI Removed]. Data package and product chemistry., DACO: 2.99
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1843541	2005, Accelerated Storage Stability of Metam potassium 690 g/L, DACO: 2.14.13
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2715833	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
2715834	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
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B. ADDITIONAL INFORMATION CONSIDERED

Published Information

PMRA

Document

Number	Reference
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2226738	Canada, 2012b. Pest Management Regulatory Agency. Re-evaluation Note REV2012-08, Chloropicrin, Dazomet, Metam Sodium and Metam Potassium - Label Improvements for Soil Fumigant Products.
2226824	Canada, 2012c. Pest Management Regulatory Agency. Re-evaluation Note REV2012-11, Label Amendments for Soil Fumigant Products Containing Metam Sodium or Metam Potassium.
2815672	United States (Date unknown). Data Evaluation Record. Special Study: Human Eye Irritation and Odor Threshold. United States Environmental Protection Agency. EPA-HQ-ORD-2006-0310-0022
2788407	United States, 2004a. Ecological Risk from Antimicrobial Uses of Metam-Sodium to be Considered in the RED Document. United States Environmental Protection Agency, April 14, 2004. EPA-HQ-OPP-2004-0159-0006
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2815789	United States, 2006b. Initial Ethical Review of MITC Human Odor Threshold and Eye Irritation Studies. United States Environmental Protection Agency. EPA-HQ-ORD-2006-0310-0007
2815794	United States, 2006c. May 2-3, 2006 EPA Human Studies Review Board Meeting Report. United States Environmental Protection Agency. EPA-HQ-ORD-2006-0310-0043
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- 2788411 United States, 2014b. Metam Potassium Registration Review Data Call-in. United States Environmental Protection Agency, August 2014. EPA-HQ-OPP-2013-0140-0038
- 2788412 United States, 2014c. Metam Sodium Registration Review Data Call-in. United States Environmental Protection Agency, August 2014. EPA-HQ-OPP-2013-0140-0039