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Proposed Re-evaluation Decision

PRVD2018-09

Dazomet and Its Associated End-use Products

Consultation Document

(publié aussi en français)

22 March 2018

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ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2018-9E (print)
H113-27/2018-9E-PDF (PDF version)

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Proposed Re-evaluation Decision

Under the authority of 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.

Dazomet is a non-selective pre-plant soil fumigant used to control pathogens including insects, nematodes, bacteria, fungi and weeds in soil. This active ingredient is also used as a material preservative in water-based materials and suspensions (for example, clay slurries, adhesives, coatings, paint and concrete admixtures) and as a slimicide in industrial process fluids (that is, pulp and paper mills, recirculating water cooling towers and industrial air washers, oilfield industry and cutting fluid).

This proposed re-evaluation decision follows risk reduction measures implemented in 2012 for dazomet 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 REV2012-10, *Label Amendments for Soil Fumigant Products Containing Dazomet*).

The soil fumigation and industrial process fluid uses of dazomet have been re-evaluated based on the health and environmental risk assessments published in the USEPA Reregistration Eligibility Decision (RED)¹ (2008) and the amended RED² (2009) documents. Additional risk assessments were conducted by the PMRA where deemed necessary. The material preservative uses of dazomet are not included in this proposed re-evaluation decision. The PMRA plans to publish a document in the future providing a broader examination of the pesticides registered for the preservation of materials (such as paint, coatings, clay slurries, adhesives and concrete), including products containing dazomet. In addition, the use of dazomet for the preservation of cutting fluid is no longer supported by the registrants. Therefore, this use was not included in the current risk assessment and will be removed from the end-use product labels.

This document presents the proposed regulatory decision for the re-evaluation of the soil fumigation and industrial process fluid uses of dazomet 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 dazomet registered in Canada for soil fumigation or use in industrial process fluids are subject to this proposed re-evaluation decision.

¹ United States, 2008c

² United States, 2009a

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, dazomet is broken down into several degradates; the primary being methyl isothiocyanate (MITC), which accounts for most of the pesticidal properties. Dazomet has value as a pre-plant soil fumigant for the control of soil pests and pathogens in Canada, which can disrupt plant growth and production. Dazomet also has value as an antimicrobial agent for control of microbial activity in industrial process fluids (that is, pulp and paper mills, recirculating water cooling towers and industrial air washers and oilfield industry).

Additional risk-reduction measures and label updates are proposed for all end-use products containing dazomet registered for soil fumigation or use in industrial process fluids to further mitigate risk to workers. Occupational risks are not expected to be of concern when products containing dazomet are used according to the proposed label directions.

Dazomet is not registered for residential use in Canada. Risk from bystander exposure is not expected to be of concern when products containing dazomet are used according to the proposed label directions.

Risk from dietary exposure is not of concern when products containing dazomet are used for soil fumigation and in industrial process fluids under the current conditions of use.

With respect to the environment, dazomet enters the environment when applied for soil fumigation. Environmental exposure from some industrial process fluid uses is expected to be minimal under the current conditions of use; however, there may be exposure to the environment from other industrial processes, such as in oilfields.

Currently registered labels include the risk reduction measures required to minimize potential exposure to non-target organisms. When used according to the current label directions, dazomet is not expected to pose risks of concern to the environment. No additional risk reduction measures are proposed. However, minor label amendments are proposed to meet current labelling standards.

Proposed Regulatory Decision for Dazomet

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 dazomet registered for soil fumigation or use in industrial process fluids are acceptable for continued registration for use and sale in Canada, provided that the proposed 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 dazomet, further risk mitigation measures and label updates are being proposed for the end-use products containing dazomet registered for soil fumigation or use in industrial process fluids, including:

- Hazard label statements for all product labels.
- Additional personal protective equipment for workers handling dazomet for use in water cooling systems and air washers.
- Closed delivery system for liquid formulations used in industrial process fluids.
- Precautionary statements regarding the need for adequate ventilation in enclosed facilities for the pulp and paper uses.

Details of the proposed label amendments are presented in Appendix III.

International Context

Dazomet is 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 31 October 2017, no decisions by any OECD member country to prohibit all uses of dazomet for health or environmental reasons have been identified.

Next Steps

Before making a final re-evaluation decision on dazomet, 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 dazomet. 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

Dazomet is registered as a pre-plant soil fumigant, as a slimicide in industrial process fluids (that is, pulp and paper mills, recirculating water cooling towers and industrial air washers, oilfield industry and cuttings fluids), and as a material preservative (for example, clay slurries, adhesives, coatings, paint, concrete admixtures). Only the soil fumigant and industrial process fluid uses of dazomet were considered as part of this proposed re-evaluation decision. The PMRA plans to publish a document in the future providing a broader examination of the pesticides registered for the preservation of materials, including products containing dazomet. In addition, the use of dazomet for the preservation of cutting fluid is no longer supported by the registrants. Therefore, this use was not included in the current risk assessment and will be removed from the end-use product labels.

Twenty-two products containing dazomet are currently registered in Canada (refer to Appendix D): four technical grade active ingredients, one manufacturing concentrate, one restricted class product and sixteen commercial class products.

The “Restricted” class end-use product is registered for pre-plant fumigation to control pathogens including insects, nematodes, bacteria, fungi and weeds in soil. Dazomet is currently registered for use in greenhouses and/or outdoors, in soil where food and non-food crops, forest nurseries, seed or propagation beds, ornamentals or turf will be planted. The end-use product, formulated as granules, is applied by hand or using ground equipment (for example, a fertilizer spreader) as a broadcast or row treatment, and incorporated into soil. The soil is sealed and is aerated prior to planting.

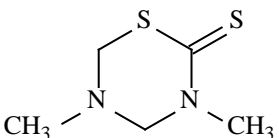
The “Commercial” class end-use products containing dazomet are registered for use as material preservatives in water-based materials and suspensions (for example, clay slurries, adhesives, coatings, paint and concrete admixtures) and as a slimicide in industrial process fluids (that is, pulp and paper mills, recirculating water cooling towers and industrial air washers, oilfield industry and cutting fluid). These products are formulated as liquids (that is, solutions, suspensions and emulsifiable concentrates) or solids (that is, granules, and wettable or soluble powders), which are added directly during the manufacturing or industrial process.

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 REV2012-10, *Label Amendments for Soil Fumigant Products Containing Dazomet*).

These measures came into force in Canada in September 2014 and were consistent with measures adopted by the United States Environmental Protection Agency (USEPA) for dazomet.^{4,5}

2.0 The Technical Grade Active Ingredient, Its Properties

2.1 Identity of the Technical Grade Active Ingredient Dazomet

Common name	Dazomet
Function	Insecticide, nematocide, bactericide, fungicide, herbicide
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	3,5-Dimethyl-1,3,5-thiadiazinane-2-thione; tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione
2 Chemical Abstracts Service (CAS)	Tetrahydro-3,5-dimethyl-2H-1,3,5,-thiadiazine-2-thione
CAS Registry Number	533-74-4
Molecular formula	C ₅ H ₁₀ N ₂ S ₂
Structural formula	
Molecular weight	162.3

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient Dazomet

Property	Result
Vapour pressure	0.58 mPa (20°C) 1.3 mPa (25°C)
Ultraviolet (UV)–visible spectrum	λ_{max} at 245 nm and 283 nm. No absorbance above 340 nm
Solubility in water at 20-25°C	3.5 g/L
<i>n</i>-Octanol–water partition coefficient	Log K_{ow} = 0.63 at pH 7
Dissociation constant	Not applicable

⁴ United States, 2008c

⁵ United States, 2009a

3.0 Impact on Human Health

Upon application, dazomet is broken down into several degradates, the primary being methyl isothiocyanate (MITC), which accounts for most of the pesticidal properties. Exposure to parent dazomet, or the degrade product (MITC), may occur while working as a primary handler (for example, while mixing, loading or applying products containing dazomet), by entering treated sites (such as fields and greenhouses), by working in industrial facilities, or through bystander exposure. 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.

3.1 Toxicology Summary

Acute studies conducted in laboratory animals indicated that dazomet is of low acute toxicity by the dermal and inhalation routes, of moderate acute toxicity via the oral route, is not a skin or eye irritant and is not a dermal sensitizer.

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

The labels of all end-use products currently require personal protective equipment, including eye protection (such as, goggles, a face shield or a full face respirator) to protect workers. Based on the high acute toxicity and irritating properties of MITC, and its potential for skin sensitization, hazard statements are proposed for the labels of all products registered for soil fumigant or industrial process fluid uses (refer to Appendix III for details).

The toxicological database for dazomet and MITC was considered complete for risk assessment purposes. The toxicological endpoints for dazomet and MITC used for assessing risk to human health are summarized in Appendix II.

3.2 Occupational Exposure and Risk Assessment

Workers can be exposed to dazomet and MITC during or after application.

Exposure to parent dazomet 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.

3.2.1 Primary Handler Exposure and Risk

3.2.1.1 Soil fumigation

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 dazomet, 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 dazomet and MITC (refer to Re-evaluation Note REV2012-10 for details). These measures include:

- personal protective equipment for all handlers;
- inclusion of respirator protection and stop work triggers on the label;
- 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 applications requirements; and
- mandatory certification or licensing required for all soil fumigant handlers.

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 dazomet 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 (refer to Section 3.1 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 (refer to Appendix III for details).

3.2.1.2 Industrial Process Fluids

When used in industrial process fluids (that is, pulp and paper mills, recirculating water cooling towers and industrial air washers and oilfield industry), dazomet is added during the industrial process as a liquid via open pour or closed system (for example, pump or gravity feed) or as a solid via a closed system (that is, in water soluble bags). Based on the current use pattern, short- to long-term dermal and inhalation handler exposure to parent dazomet can occur when the

product is being added to the industrial process (for example, loading of the product, connecting/disconnecting a chemical metering pump from a tote). Handler exposure to MITC is not expected to occur since there will be insufficient time for dazomet to convert to MITC during handling.

As part of the re-evaluation, risk reduction measures were implemented in Canada to protect primary handlers from dermal and inhalation exposures to dazomet when used for the preservation of industrial process fluids (refer to Re-evaluation Note REV2012-07 for details). 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 are currently included on the end-use product labels. Additional risk reduction measures or clarifications to the labels, outlined below, are however needed to further protect workers from exposure to dazomet.

The potential risk to handlers is not expected to be of concern for workers adding dazomet to tanks for oilfield uses, or in pulp and paper mills, using a closed application system and wearing the personal protective equipment currently required on the product labels⁶. The labels of certain end-use products formulated as liquids do not clearly specify the use of a closed application system. Therefore, for consistency and to improve clarity, application via a closed system is proposed for all end-use products formulated as liquids registered for use in the oilfield industry or in pulp and paper mills (refer to Appendix III for details).

A potential risk of concern was identified for workers applying dazomet in recirculating water cooling systems and industrial air washers under the current conditions of use (which include personal protective equipment consisting of single layer clothing plus chemical-resistant gloves). On this basis, additional personal protective equipment (that is, coveralls over single layer clothing plus chemical-resistant gloves) and application via a closed system are proposed for these uses to minimize potential exposure of workers during application (refer to Appendix III for details).

Based on the proposed revised conditions of use, the risk to primary handlers involved in the application of dazomet in industrial process fluids is not expected to be of concern.

⁶ Chemical-resistant coveralls over single layer clothing plus chemical-resistant gloves for the oilfield use and coveralls over single layer clothing plus chemical-resistant gloves for the pulp and paper use.

3.2.2 Postapplication Exposure and Risk

3.2.2.1 Soil Fumigation

Because dazomet rapidly degrades to MITC following application, postapplication exposure to the parent compound 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 dazomet is 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 (refer to Re-evaluation Note REV2012-10 for details), and are currently included on the product labels:

- mandatory GAPs to reduce emissions from treated fields (refer to Section 3.2.1.1);
- 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 (refer to Section 3.3.1.1);
- site-specific Fumigation Management Plan (FMP), which cover 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 dazomet as a soil fumigant are not of concern based on the current conditions of use; therefore, no additional risk reduction measures are proposed.

3.2.2.2 Industrial Process Fluids

The potential for postapplication worker exposure to dazomet or MITC from the use of dazomet in recirculating cooling water systems and industrial air washers, and in the oilfield industry, is expected to be negligible since, once the application is complete, the remainder of the process is expected to occur in entirely closed systems. On this basis, risk from occupational postapplication exposure is not expected to be of concern, and no additional risk reduction measure is proposed for these uses.

Dazomet rapidly hydrolyses to MITC when mixed with water. On this basis, postapplication worker exposure to the parent compound is not expected as a result of the use of dazomet in pulp and paper mills. There is potential for short- to long-term postapplication inhalation exposure to MITC in pulp and paper mills because of MITC's high volatility. The labels of several end-use

products registered for use in pulp and paper mills currently include instructions to minimize the potential for postapplication inhalation exposure (for example, “*Use with adequate ventilation*” and “*Do not apply the product in open systems*”). For consistency, and to minimize the potential for postapplication inhalation exposure to MITC in pulp and paper mills, these label statements are proposed for all end-use products registered for this use.

Based on the proposed revised conditions of use, risk from postapplication inhalation exposure to MITC from the use of dazomet in industrial process fluids is not expected to be of concern.

3.3 Non-Occupational Exposure and Risk Assessment

3.3.1 Residential Exposure

There are no domestic end-use products currently registered for dazomet. However, based on MITC’s high volatility, residential bystander exposure is possible following soil fumigant applications. The use of dazomet in industrial process fluid is not expected to result in residential exposure.

3.3.1.1 Soil Fumigation

MITC released from treated soil following application of dazomet can move off-site to non-target areas and result in residential bystander exposure.

Extensive risk reduction measures were implemented in Canada as part of the re-evaluation to minimize bystander exposure to MITC following dazomet soil fumigant applications (refer to Re-evaluation Note REV2012-10 for details). The measures include:

- mandatory GAPs to reduce emissions from treated fields (refer to Section 3.2.1.1);
- site-specific Fumigation Management Plan (FMP) (refer to Section 3.2.2.1), 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. Based on this, the potential risk to bystanders is not expected to be of concern based on the current conditions of use. No additional mitigation measure is proposed.

3.3.2 Dietary Exposure and Risk

3.3.2.1 Soil Fumigation

Dazomet is registered for use as a pre-plant soil fumigant on greenhouse and outdoor soil where food crops will be planted. Dazomet rapidly degrades to MITC upon application. Based on MITC's rapid dissipation in the environment (refer to Section 4.1 for details) and on the results of available metabolism studies in plants, no residues are expected to be present in food from the registered use for pre-plant soil fumigation.

Due to the rapid degradation of dazomet to MITC in the environment, there is a low potential for the parent compound to be present in drinking water following soil fumigant applications of dazomet. Under most field conditions, the potential for drinking water contamination of MITC is expected to be minimal due to its volatilization and fast degradation in soil (refer to Section 4.1 for details).

On this basis, risk from potential dietary exposure from the use of dazomet as a soil fumigant is not expected to be of concern.

3.3.2.2 Industrial Process fluids

Due to the rapid degradation of dazomet to MITC when mixed with water, there is a low potential for the parent compound to be present in drinking water following the use of dazomet in industrial process fluid. Based on the fate characteristics of MITC, the potential for drinking water contamination is expected to be minimal because MITC is expected to dissipate quickly in the environment (refer to Section 4.1 for details).

On this basis, risk from potential dietary exposure as a result of the use of dazomet in industrial process fluids is not expected to be of concern.

3.3.3 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 dazomet or MITC in food and drinking water is expected to be minimal (refer to Section 3.3.2 for details). As discussed in Section 3.3.1, there are no domestic-class end-use products containing dazomet registered in Canada. Given the limited potential for bystander (refer to Section 3.3.1 for details) and dietary exposures under the current conditions of use, aggregate exposure is expected to be minimal and risks are not expected to be of concern for currently registered uses.

3.3.4 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 commercial and industrial use pattern of dazomet, and that dietary or residential exposure for dazomet and MITC are expected to be limited under the proposed revised conditions of use, there is no requirement for a cumulative risk assessment at this time.

4.0 Environmental Assessment

4.1 Fate and Behaviour in the Environment

Dazomet is non-volatile and readily soluble in water (solubility in water of 3.5 g/L at 25°C). Dazomet is subject to hydrolysis (half-lives at pH 3 to 9 ranging from 4 to 6.8 hours), and photolysis in soil (half-life of 9-10 days) and water (half-life of 4 hours at pH 7). Dazomet degrades very rapidly in terrestrial and aquatic environments (half-life of 17.2 and 3 hours in aerobic soil and anaerobic water/sediment systems, respectively). The major degradation product of dazomet in water and soil is MITC.

MITC is highly soluble in water (solubility in water of 7.6 g/L at 20°C) and has low adsorption in soil (K_d of 0.26 L/kg). MITC is subject to hydrolysis (half-lives ranging from 3.5 to 20.4 days at pH 5-9), and to photolysis in air (photodegradation half-life in air of 1.21-1.60 days) and water (photodegradation half-life in water of 51.6 days). Based on its high vapour pressure and Henry's Law Constant, MITC is expected to volatilize from fields treated with dazomet and from water.

Based on dazomet and MITC's octanol/water partition coefficients ($\log K_{ow} = 0.15$ and 0.98 for dazomet and MITC, respectively), 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 was not detected in the available groundwater monitoring data. MITC can also potentially move to surface water through runoff. However, it is expected to volatilize rapidly from surface water.

4.2 Environmental Risk Characterization

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

4.2.1 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 in 2012 as part of the re-evaluation for the soil fumigant product containing dazomet to further protect human health and the environment (refer to REV2012-10 for details). Further, the risk reduction measures aimed at minimizing the release of MITC from treated fields (for example, mandatory good agricultural practices (GAPs), refer to Section 3.2.1.1) will mitigate potential environmental exposure.

The implemented risk reduction measures will also reduce ecological risks by providing an incentive to reduce fumigant application rates and individual treatment areas.

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 product registered for use as a soil fumigant. The product label also include precautionary statements related to preventing the release of greenhouse effluent into the aquatic environment and the contamination of aquatic habitats by cleaning of equipment or disposal of wastes.

The implemented mitigation measures are expected to mitigate potential risk to non-target organisms. No further risk reduction measures are proposed. Minor label amendments are proposed to meet current labelling requirements (refer to Appendix III).

4.2.2 Industrial Process Fluids

The labels of all dazomet products registered for use in industrial process fluids currently includes precautionary label statements pertaining to the toxicity to aquatic organisms and directions for use prohibiting effluent discharge into aquatic environments. Thus, under the current conditions of use, minimal release of MITC into the environment is expected from the use of dazomet in recirculating cooling water systems and industrial air washers, or in pulp and paper mills.

Environmental exposure resulting from use in on-shore oilfield production (including the treatment of secondary recovery water) may occur; however, this use pattern 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 because fluids are recycled. Further, MITC introduced into the environment as a result of the use of dazomet in industrial process fluids will dissipate quickly through volatilization, followed by photolytic degradation in the atmosphere, and is not expected to persist in the environment.

Based on the above, risk to non-target organisms is not expected to be of concern for the industrial process fluid uses of dazomet under the current conditions of use. No additional risk reduction measure is 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 product labels. An updated Direction for Use statement pertaining to effluent discharge and an updated precautionary statement related to the toxicity to aquatic organisms are also proposed (refer to Appendix III).

5.0 Value

Dazomet has value as a pre-plant soil fumigant. 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.

Dazomet also has value as an antimicrobial agent for control of microbial activity in industrial process fluid (for example, pulp and paper mills, water cooling towers, oilfield industry).

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03,⁷ the assessment of dazomet and its transformation products against Track 1 criteria of the Toxic Substances Management Policy (TSMP) under the *Canadian Environmental Protection Act* was conducted. It determined that:

- Dazomet does not meet all Track 1 criteria, and is not considered a Track 1 substance. The half-lives of dazomet 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 dazomet and MITC are below the Track 1 criterion.
- Dazomet does not form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada*

⁷ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

Gazette.⁸ The list is used as described in the PMRA Notice of Intent NOI2005-01⁹ and is based on existing policies and regulations including DIR99-03 and DIR2006-02,¹⁰ 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.

7.0 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 dazomet.

As of 28 July 2017, no human or domestic animal incidents were reported to the PMRA for dazomet, and one environmental incident report involving this active ingredient had been submitted. Dazomet 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 dazomet 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 dazomet incidents that were available (version of 5 October 2015). Three incidents in the EIIS database were considered to be possibly associated with the reported exposure to dazomet. All three incidents resulted in the death of fish and aquatic invertebrates after runoff from the application site in two cases, and a spill in the third case.

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

⁸ *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.*

⁹ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

¹⁰ DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

8.0 Conclusions

Upon application, dazomet is broken down into several degradates; the primary being methyl isothiocyanate (MITC), which accounts for most of the pesticidal properties. Dazomet has value as a pre-plant soil fumigant. 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. Dazomet also has value as an antimicrobial agent for control of microbial activity in industrial process fluids (that is, pulp and paper mills, water cooling towers and air washers and oilfield industry).

Occupational risks are not expected to be of concern when products containing dazomet are used according to the proposed label directions, which include protective measures. Dazomet is not registered for residential use in Canada. Risk from bystander exposure is not expected to be of concern when products containing dazomet are used according to the proposed label directions. Risk from dietary exposure is not of concern for all registered uses under the current conditions of use.

With respect to the environment, dazomet enters the environment when applied for soil fumigation. Environmental exposure from some industrial process fluid uses is expected to be minimal under the current conditions of use; however, there may be exposure to the environment from other industrial processes, such as uses in oilfields. Dazomet breaks down quickly to MITC and is 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. Dazomet 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. When used according to the label directions, dazomet is not expected to pose risks of concern to the environment. No additional risk reduction measures are proposed. However, minor label amendments are proposed to meet current labelling standards.

Appendix I Registered Pest Control Products Containing Dazomet

Table 1 Registered Dazomet Products as of 5 January 2018

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
18873	T	Lanxess Corporation*	N-521 Biocide	Solid	97
19413	T	Engage Agro Corporation*	Technical Dazomet (Basamid Granular)	Granular	97
23295	T	Kemira Chemicals, Inc.*	AMA-35 D-C	Granular	98
25256	T	Buckman Laboratories of Canada Ltd.*	Thion Microbicide	Granular	98.0
19719	M	BASF Canada Inc.*	Myacide DZ	Granular	97.0
15032	R	Engage Agro Corporation*	Basamid Granular Soil Fumigant	Granular	97.00
14645	C	Nalco Canada ULC	Nalcon D3T-A	Solution	21
14647	C	Nalco Canada ULC	Nalcon 7616	Wettable Powder	97
23954	C	Kemira Chemicals, Inc.*	AMA-35D-PC	Granular	98
24065	C	Kemira Chemicals, Inc.*	AMA-20-C	Suspension	20
24065.01	C	Dubois Chemicals Canada, Inc.	X-CELL 425LC	Suspension	20
24755	C	Lanxess Corporation*	N-521® PAC-24	Solution	24
26404	C	Buckman Laboratories of Canada Ltd.*	Busan 1058 Liquid Microbicide	Solution	24.0
27138	C	Buckman Laboratories of Canada Ltd.*	Busan 1124 Microbicide	Emulsifiable Concentrate or Emulsion	24
27166	C	Buckman Laboratories of Canada Ltd.*	Busan 1059 WS	Wettable Powder	98
27171	C	Lanxess Corporation*	N-521 Dispersion	Suspension	19.8
27830	C	Dubois Chemicals Canada, Inc.	B.I.O. Blast 100S	Soluble Powder	97
27875	C	Solenis canada ulc	Spectrum RX3500	Suspension	19.4
29739	C	Kemira Chemicals, Inc.*	AMA 424-C Antimicrobial Agent	Solution	24
29969	C	Kemira Chemicals, Inc.*	AMA 324-C Antimicrobial Agent	Solution	24
31480	C	CESI Chemical	AMB-100	Solution	24
32591	C	Kemira Chemicals, Inc.*	AMA-924-C Antimicrobial Agent	Solution	24

Appendix II Toxicological Reference Doses for Health Risk Assessments

Table 1 Toxicology Reference Doses for Use in Health Risk Assessments for Dazomet

Exposure Scenario	Dose ^a (mg/kg bw/day)	Study	UF ^b
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 and inhalation ^c (1-30 days)	oral NOAEL = 15 mg/kg/day	Acute neurotoxicity study LOAEL = 50 mg/kg bw/day Based on neurobehavioral effects FOB findings and reduced number of rearings.	Occupational LOC for MOE = 100 ^d
Intermediate-term dermal and inhalation ^c (1-6 months)	oral NOAEL = 1.5	Subchronic toxicity- feeding rats LOAEL = 4.5 mg/kg bw/day Based on increased liver weight, liver:body weight ratio and pronounced foci of fatty degeneration in the liver	Occupational LOC for MOE = 100 ^d
Long-term dermal and inhalation (>6 months) ^c	NOAEL = 0.35 mg/kg bw/day	Chronic toxicity study in dog LOAEL = 1.15 mg/kg bw/day Based on increased liver to body weight ratio and increased pigmentation in the liver	100
Dermal Absorption ^e	13%		
Cancer (oral, dermal, inhalation)	Classification: Not classifiable as human carcinogen.		

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

^b LOC = Level of concern; MOE = Margin of exposure; UF = uncertainty factor

^c Based on information available in United States 2008a, United States, 2009b.

^d MOE = 100 (10× for interspecies extrapolation, 10× for intraspecies variations)

^e Based on information available in European Union, 2010.

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

Exposure Scenario	Dose ^a (mg/kg bw/day)	Study	UF ^b
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 End-Use Products Containing Dazomet

The label amendments presented below 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 label statements below.

The labels of end-use products registered in Canada must be amended to include the following statements:

- I) The use of dazomet as a preservative of cutting fluid must be removed from the end-use product labels.
- II) For technical grade, manufacturing concentrates and end-use products containing dazomet, 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

- III) In the **NATURE OF RESTRICTION** section of the primary display panel of the end-use product 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.

IV) The following statements 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 use in recirculating water cooling systems and industrial air washers:

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.

For end-use products registered for pulp and paper uses:

Use with adequate ventilation. DO NOT apply the product in open systems.

V) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

For liquid end-use products (for example, solutions, suspensions, emulsifiable concentrates) registered for use in oilfield, pulp and paper, or recirculating water cooling systems and industrial air washer:

For use with closed loading and transfer systems only.

For end-use products registered for industrial process fluid uses:

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 all end-use products:

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

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

VI) The following statement must be included in a section entitled **ENVIRONMENTAL PRECAUTIONS**:

For all end-use products:

Toxic to aquatic organisms.

VII) The following statement 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

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2715829	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
2715830	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
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2715835	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
2715836	Combined chronic/oncogenicity (rodent), Daco: 4.4.4
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B. ADDITIONAL INFORMATION CONSIDERED

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