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Re-evaluation Decision

RVD2015-03

Aluminum/Magnesium Phosphide and Phosphine Gas

(publié aussi en français)

27 August 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada 

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2015-3E (print version)
H113-28/2015-3E-PDF (PDF version)

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Re-evaluation Decision

After a re-evaluation of fumigants containing aluminum phosphide, magnesium phosphide or phosphine gas, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing these chemicals for sale and use in Canada. However, as a requirement for continued registration, new and revised risk mitigation measures must be included on all labels of currently registered products.

The regulatory approach for the re-evaluation of these chemicals was first presented in Proposed Acceptability for Continuing Registration PACR2004-43, *Re-evaluation of Aluminum and Magnesium Phosphide*,¹ a consultation document.² The PMRA published Re-evaluation Note REV2007-06, *Aluminum and Magnesium Phosphide Interim Measures* and REV2010-03, *Aluminum and Magnesium Phosphide*³ requiring mitigation measures to address potential human health risk concerns. The present re-evaluation decision⁴ describes the additional risk mitigation measures that are required to be implemented on all products.

To comply with this decision, new and revised risk mitigation measures should be implemented as soon as possible, but no later than 30 June 2016. Starting 1 July 2016, all products sold must bear a new label which includes the new mitigation measures. Registrants of end-use products containing these chemicals will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What are Aluminum/Magnesium Phosphide and Phosphine Gas?

Aluminum and magnesium phosphide react with moisture in the air to release hydrogen phosphide (phosphine) gas. Hydrogen phosphide gas acts as a fumigant to control a wide variety of arthropods (including insects), nematodes and rodents. Aluminum phosphide, magnesium phosphide and phosphine gas are registered as Restricted Class products in Canada and must be applied by licensed or certified applicators trained in the use of these fumigants. These products are applied in the treatment of stored commodities, such as raw agricultural products, feed, processed foods, stored tobacco and non-food materials and may be used to fumigate a broad variety of structures such as storage bins, grain elevators, food processing plants, mills, warehouses, and transport vehicles (for example, ships, railcars, trucks). In addition, aluminum phosphide may be applied as a rodenticide to control woodchucks, groundhogs and Richardson's ground squirrels in rodent burrows located in non-residential areas. Products containing aluminum or magnesium phosphide are formulated as tablets or pellets and phosphine gas is packaged as a compressed gas cylinder.

¹ PACR2004-43, *Re-evaluation of Aluminum and Magnesium Phosphide*, 26 November 2004.

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

³ REV2007-06, *Aluminum and Magnesium Phosphide Interim Measures*, 1 June 2007.
REV2010-03, *Aluminum and Magnesium Phosphide*, 24 August 2010.

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

Additional Risk Mitigation Measures

The PMRA is requiring the implementation of additional risk mitigation measures for all fumigated sites to further limit potential exposure to workers and bystanders (Appendix I). A summary of the additional risk mitigation measures is outlined below:

- A minimum buffer zone of 200 metres must be established for difficult-to-evacuate sites. These sites include schools, daycare centres, nursing homes, assisted-living facilities, hospitals, in-patient clinics, and prisons.
- To further protect workers and bystanders, a minimum buffer zone of 50 metres must be established for all fumigated sites.

With respect to rodent burrow treatment on farms, this means 50 metres from buildings that are or may be occupied by humans, and/or domestic animals, and that are under the control of the owner/operator of the application site; otherwise a 500 metre restriction is applicable.

This minimum buffer zone of 50 metres is not required for ships and railcars that are in motion (in other words, moving in transit).⁵ However, this minimum buffer zone must be established for stationary ships in Canadian waters, ports and harbours, as well as for fumigated railcars while located at rail terminals and for any prolonged stops en route. The person in charge of the train is responsible for ensuring that buffer zone requirements are adhered to for any prolonged stops en route. New label mitigation measures are required specifying that railway vehicles containing treated commodities must be placed as far as possible from occupied train compartments, in order to minimize exposure to crew during in-transit fumigations.

Note that transport of non-aerated commodities is permitted by rail or ship only. Other transport vehicles such as trucks, vans and trailers, are prohibited from travel over public roads or highways until completely aerated to a hydrogen phosphide level at or below 0.1 ppm.

⁵ Shipboard, in-transit ship or shiphold fumigation is also governed by the *Canadian Shipping Act* and Transport Canada Ship Safety Regulations (refer to: Cargo, Fumigation and Tackle Regulations under the *Canada Shipping Act*, updated 2013).

- Once a buffer zone is established, applicators must continually monitor hydrogen phosphide (phosphine) gas levels at several locations along the buffer zone perimeter. If hydrogen phosphide gas concentrations approach the limit restriction of 0.1 ppm, the applicator must take appropriate action such as extending the buffer zone.

This approach is consistent with existing fumigation practices in Ontario, regulated by the Ministry of Environment, and in Germany where the use of monitored fumigation boundaries are required for phosphine.

Additional Revisions to the Product Label (which includes the Applicator's Manual)

- To reduce the need for fumigant use, an operational pest management plan should be put in place in food processing facilities and/or sites where insects/rodents forage or seek refuge in order that the facility, its equipment and its exterior surroundings do not promote pest populations, and are amenable to control and treatment methods (Appendix I).
- A number of label improvements applicable to the product label (which includes the Applicator's Manual) have been identified in order to align current wording with the new mitigation measures described in this document. Additional improvements to the product label have also been identified to provide clarity in areas such as the use directions. To comply with the implementation of these improvements, registrants will be informed of the specific changes affecting their product labels. Revisions include updates to the following areas:
 - Precautions;
 - Respiratory protection and personal protective equipment;
 - Environmental hazards;
 - Fumigation Management Plan;
 - Use directions;
 - Disposal and deactivation;
 - Spill and leak procedures.

Other Information

Any person may file a notice of objection⁶ regarding this decision within 60 days from the date of publication of this document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

⁶ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Summary of Required Amendments and Additional Risk Mitigation Measures

For All End-Use Products (except those used only for rodent control in burrows)

1. Additional Key Safety Information on the Product Label (which includes the Applicator's Manual)

Add under the NATURE OF RESTRICTIONS section:

The use of this product is RESTRICTED due to the high acute inhalation toxicity of hydrogen phosphide (phosphine, PH₃) gas.

A minimum buffer zone of 50 metres must be established for all fumigated sites (with the exception of ships and railcars that are in motion), refer to the Applicator's Manual – BUFFER ZONE REQUIREMENTS. Note that the term "fumigated site/application site" refers to the site under fumigation treatment. Placarding is required for both the fumigated site and the buffer zone perimeter.

Note that transport of non-aerated commodities is permitted by rail or ship only. Other transport vehicles such as trucks, vans and trailers, are prohibited from travel over public roads or highways until completely aerated to a hydrogen phosphide level at or below 0.1 ppm.

Appropriate respiratory protection, as outlined in the Applicator's Manual – RESPIRATORY PROTECTION, must be worn during delivery/dispensing of product, while attending to spills and leaks, during deactivation of unreacted granules, and while monitoring hydrogen phosphide levels during the fumigation and aeration periods (in other words, worn at all times when levels of hydrogen phosphide gas are above 0.1 ppm or are unknown). Entry by unprotected workers is only permitted after the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

2. Addition of Pest Management Section on Label

Create a new section on the label entitled **PEST MANAGEMENT PRACTICES** containing the following text:

An operational pest management plan should be put in place in food processing facilities and/or other relevant sites where insects/rodents forage or seek refuge in order that the facility, its equipment and its exterior surroundings do not promote pest populations, and are amenable to control and treatment methods. The plan should include the following:

- *Practices to reduce or eliminate infestations in incoming food and ingredients through strict purchase specifications, audits of suppliers, and inspection of incoming material.*

- *Good sanitation practices involving thorough and regular cleaning, prevention of dust generation and accumulation, and removal of food sources and harbourages for pests.*
- *Building maintenance to eliminate holes and cracks in floors, walls, ceilings, roofs, doors and windows that allow access for pests.*
- *Regular inspections and monitoring to guide schedules and locations of treatments, and to monitor the effectiveness of the overall management strategy.*
- *Pest identification and understanding of each pest's lifecycle to select the most appropriate control methods.*
- *Other practices including physical and mechanical treatments, controlled atmospheres, and applications of registered pesticides. Each treatment should be used as one component of an overall pest management plan. All pesticides must be stored, handled, and used according to label instructions.*

3. Establishment of Buffer Zones – Applicator's Manual

- i) Under the Safety Recommendations Summary, the following statements must be added:

*A minimum buffer zone of 50 metres must be established for all fumigated sites (with the exception of ships and railcars that are in motion) as per the instructions outlined under the section, **BUFFER ZONE REQUIREMENTS**.*

Note that transport of non-aerated commodities is permitted by rail or ship only. Other transport vehicles such as trucks, vans and trailers, are prohibited from travel over public roads or highways until completely aerated to a hydrogen phosphide level at or below 0.1 ppm.

- ii) Create a new section entitled **BUFFER ZONE REQUIREMENTS** following the **RESPIRATORY PROTECTION** section and immediately preceding the **APPLICATOR AND WORKER EXPOSURE** section.

Add the following information:

Buffer Zones

A buffer zone is an area established around the perimeter of the application site where a hydrogen phosphide (phosphine) gas-releasing fumigant is applied.

The following describes the general buffer zone requirements:

- *A minimum buffer zone of 50 metres must be established for all fumigated sites (with the exception of ships and railcars that are in motion). Note that transport of non-aerated commodities is permitted by rail or ship only. Other transport vehicles such as trucks, vans and trailers, are prohibited from travel over public roads or highways until completely aerated to a hydrogen phosphide level at or below 0.1 ppm.*
- *The buffer zone must extend from the perimeter of the application site equally in all directions.*

- *All non-handlers including workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone (i.e. not present) during the application and until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.*
- *A buffer zone must be established prior to application, when the fumigant is delivered/dispensed to the application site. The buffer zone must be maintained until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.*
- *Appropriate respiratory protection (as outlined in the **RESPIRATORY PROTECTION** section) must be worn if entry into the fumigated site and the buffer zone is required at any point from the beginning of application until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.*
- *If an extension of the buffer zone is required due to levels of hydrogen phosphide greater than 0.1 ppm, the provisions in the **Areas Not Under the Control of Owner/Operator of the Application Site** section must be followed.*

Extension of Buffer Zone As A Result of Monitoring

From the beginning of the fumigant application until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone, a supervising fumigant applicator/handler or someone under his/her supervision must continually monitor hydrogen phosphide levels at several locations along the buffer zone perimeter.

If at any time the person monitoring hydrogen phosphide levels detects concentrations greater than 0.1 ppm, the buffer zone must be extended until the hydrogen phosphide is at or below 0.1 ppm along the perimeter. If an extension of the buffer zone is not feasible, appropriate measures must be implemented (e.g. cease the delivery/dispensing of product, sealing of leaks, limiting aeration) until the hydrogen phosphide level is at or below 0.1 ppm at the buffer zone perimeter at which time fumigation activities may continue.

Authorized Entry to Buffer Zones

Only authorized pesticide applicators/handlers wearing appropriate personal protective equipment may be in the buffer zone during the fumigation and aeration periods. All non-handlers including workers, nearby residents, pedestrians, and other bystanders, must be excluded from the buffer zone (i.e. not present) during the application and until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

Structures Under the Control of Owner/Operator of the Application Site

The buffer zone must not include within it any structures UNLESS they are unoccupied during the application. Entry into these structures is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

See the *PLACARDING OF FUMIGATION AREAS* for additional requirements that may apply.

Areas Not under the Control of Owner/Operator of the Application Site

a. Agricultural areas

The buffer zone must not include within it any agricultural areas owned/operated by persons other than the owner/operator of the application site to be fumigated UNLESS, persons who own/operate an adjacent area (such as areas that are not under the control of the owner/operator of the application site) provide explicit written confirmation to the supervising fumigant applicator/handler that they, their employees, and any other persons will not be present during the entire fumigation and aeration periods. Entry into these areas is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

b. Roads and rights of way

The buffer zone must not include within it any roads and rights of way UNLESS the area is not occupied during the application. Entry into these areas is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

c. All other publicly owned and/or operated areas

For all other publicly owned and/or operated areas, such as parks, sidewalks, walking paths, playgrounds and athletic fields, the buffer zone must not include these areas within it UNLESS,

- *The public area is not occupied during the fumigation and aeration periods and entry into the area is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone, and*
- *Explicit written permission to include the public area within the buffer zone is provided to the supervising fumigant applicator/handler and/or the owner/operator by the appropriate provincial/territorial and/or local authorities responsible for the management and operation of the area.*
 - *See the *PLACARDING OF FUMIGATION AREAS* for additional requirements that may apply.*
 - *It is the responsibility of the supervising fumigant handler to record this information in the Fumigation Management Plan.*

d. Difficult-to-Evacuate Sites

Difficult-to-evacuate sites include schools (preschool to grade 12), provincially licensed day care centres, nursing homes, assisted-living facilities, hospitals, in-patient clinics, and prisons.

No fumigant application is permitted within 200 metres of the sites listed above UNLESS the site is not occupied during the fumigation and aeration periods. Entry into these sites is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

e. All other residential areas

The buffer zone must not include within it any residential areas (such as employee housing, private property, commercial buildings, and other areas that people may occupy or outdoor residential areas, such as lawns, gardens, or play areas, etc.) UNLESS the occupants in the area provide explicit written confirmation to the supervising fumigant applicator/handler and/or the owner/operator that all premises will be vacated during the fumigation and aeration periods.

Entry by occupants and other non-handlers is not permitted until the fumigated site has been aerated and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.

4. Revisions to Required Signage– Applicator’s Manual

The following information must be added to the PLACARDING OF FUMIGATION AREAS:

Additional warning signs are required along the buffer zone perimeter, and must:

- i. Be placed at all usual points of entry and along other likely routes of approach where people not under the land operator’s control may be in close proximity to the buffer zone.*
 - Some examples of points of entry include, but are not limited to, roadways, sidewalks, paths, and bike trails.*
 - Some examples of likely routes of approach are the area between a buffer zone and a roadway, or the area between a buffer zone and a housing development.*
 - Posting of warning signs for the buffer zone is required, UNLESS there is a physical barrier that prevents access into the buffer zone.*
 - Signage must not be removed until the fumigated site has been aerated, and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.*
 - Only a licenced/certified applicator can authorize removal of warning signs.*
- ii. Bear the following:*
 - The signal word DANGER in letters at least 7 cm high and the skull and crossbones symbol in red.*
 - The “DO NOT WALK” symbol.*
 - The statement, “Area under fumigation, DO NOT ENTER.”*
 - The statement, “This sign may only be removed after the fumigated site has been aerated, and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone.”*
 - Name of fumigant used: [name of product, registration number].*
 - The date and time when fumigation begins and the date and time when aeration can begin.*
 - Contact information (name, address and telephone number) for the supervising fumigant handler in charge of the fumigation.*
 - A 24-hour emergency response telephone number.*

5. Revisions to FUMIGATION MANAGEMENT PLAN – Applicator’s Manual

The following revisions are required under the section A CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN:

- i) Section A. PRELIMINARY PLANNING AND PREPARATION, **3. Fully acquaint yourself with the site and commodity to be fumigated**, add:

Buffer zone requirements, including provisions for areas not under the control of the owner/operator of the application site (e.g. agricultural areas, roads and rights of way, publicly owned and/or operated areas, difficult to evacuate sites and other residential areas).

- ii) Section **C. Monitoring, 1. Safety**:

Add the following statements:

From the beginning of the fumigant application and until the fumigated site has been aerated, and the hydrogen phosphide level is at or below 0.1 ppm in the fumigated site and the buffer zone, a supervising fumigant applicator/handler or someone under his/her supervision must continually monitor hydrogen phosphide levels at several locations along the buffer zone perimeter.

If at any time the person monitoring hydrogen phosphide levels detects hydrogen phosphide concentrations greater than 0.1 ppm, the buffer zone must be extended until the hydrogen phosphide level is at or below 0.1 ppm along the perimeter. If an extension of the buffer zone is not feasible, appropriate measures must be implemented (e.g. cease the delivery/dispensing of product, sealing of leaks, limiting aeration, etc.) until such time that the hydrogen phosphide level is at or below 0.1 ppm at the buffer zone perimeter at which time fumigation activities may continue.

Delete the following statements:

Outdoor air monitoring must be conducted during fumigation and aeration and corrective action must be taken if gas levels exceed the allowed levels in an area where bystanders and/or nearby residents or domestic animals may be located. Monitor gas levels at the fumigation boundary (downwind locations) continuously for one hour, commencing six hours after the introduction of phosphine gas, followed by once every six hours to the beginning of aeration. During aeration, monitor gas levels continuously until the structure is ready for entry.

6. Revisions to DIRECTIONS FOR USE – Applicator’s Manual

- i) Under **General**, add the following statement:

*A minimum buffer zone of 50 metres must be established for all fumigated sites (with the exception of ships and railcars that are in motion) as per the instructions outlined under the section, **BUFFER ZONE REQUIREMENTS**. Prior to entry by unprotected workers, the fumigated site must be aerated and the hydrogen phosphide level must be at or below 0.1 ppm in the fumigated site and the buffer zone.*

- ii) Under **Fumigation of Railcars, Containers, Trucks, Vans and Other Transport Vehicles and Small Storages**

Revise the title to:

Fumigation of Railcars, Containers, Trucks, Vans and Other Transport Vehicles, and Small Storages Shipped Piggyback by Rail

Add the following:

During transport, railcars containing non-aerated bulk commodities must not be located directly adjacent to another railcar containing workers or other individuals, unless it is likely to have a serious impact on train dynamics. Railcars containing fumigated cargo should be placed as far as possible from occupied cars.

*If prolonged/extended stops are required while en route (e.g. to accommodate use of rest facilities or bunkhouses) buffer zone requirements around the fumigated cargo must be followed (as outlined under section, **BUFFER ZONE REQUIREMENTS**).*