

## Evaluation Report for Category B, Subcategory 3.13 Application

**Application Number:** 2016-4991  
**Application:** Changes to Product Labels - Precautions  
**Product:** Degesch Phostoxin Tablets  
**Registration Number:** 15736  
**Active ingredients (a.i.):** Aluminum Phosphide  
**PMRA Document Number:** 2751788

### Background

Degesch Phostoxin Tablets was first registered in July 1979. This is an insecticide used to control pests in stored grain, processed foods, feeds and non-food commodities, including tobacco. This restricted class product can only be used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency or a trained professional working under the direct supervision of an individual with an appropriate certificate/licence.

### Purpose of Application

The purpose of this application was to amend the precautionary statements, including the buffer zones, on the Degesch Phostoxin Tablets label.

### Health Assessments

The Phosphine Producers Association (PPA) submitted additional data to amend the 30-metre buffer zone for hydrogen phosphide releasing products. The data package included a modified version of the data previously submitted along with new data collected in 2016. The data collected by the Canadian Grain Commission (CGC) and Western Grain Elevator Association (WGEA), referred to as the Canadian Grain Study, were also included, to further support the request to amend the buffer zones.

The amended PPA study included spot samples collected in 2016, as well as additional information such as the active ingredient used, when the sample was taken (i.e., fumigation/aeration), distances from the application site in cases where it was not previously specified, and additional information regarding the two data points that were greater than 0.1 ppm at 28 and 30 metres. The Canadian Grain study consisted of a total of 13682 spot samples collected across Canada during fumigations at grain bins (7415), processing elevators/structural (500), containers (2881), and vessels (2886). The study did not include sampling around railway cars and outdoor tarpaulins.

The results of the grain industry study show that the occurrence of phosphine concentrations greater than 0.1 ppm during fumigation is infrequent and in areas close to the fumigation site. This is similar to the findings from the PPA study during fumigation. During aeration, the PPA data also suggested that phosphine levels greater than 0.1 ppm are transient in nature as most (99%) occurred within the first 2 hours of aeration. These findings support revisions to the buffer zone in certain scenarios, provided that a risk mitigation strategy is implemented to further reduce any potential exposure to phosphine that may occur from use of the product.

Since the occurrence of samples greater than 0.1 ppm was infrequent in both studies, authorized personnel may be permitted to be present within the buffer zone to conduct necessary activities, provided that they are wearing a personal hydrogen phosphide monitor or a respirator. In order to ensure that all workers who could potentially be exposed to phosphine are aware that a hydrogen phosphide-releasing product is being used, and of safety procedures, health effects and exposure limits, all workers are required to undergo annual training as part of the risk mitigation strategy. As shown in these studies, levels of phosphine gas exceeding 0.1 ppm are possible in areas close to the fumigation site, although infrequent. The required training will allow workers to adequately respond when phosphine levels exceed the 0.1 ppm exposure limit, by either wearing personal protective equipment or vacating the premises.

For indoor application sites, a reduction of the minimum buffer zone from 30 metres to 10 metres may be supported based on the results of the grain industry study, which demonstrated that gas measurements greater than 0.1 ppm were detected up to 10 metres away from the fumigation site in grain handling and processing facilities. For outdoor containers, although there were detections of phosphine levels greater than 0.1 ppm during fumigation, they were isolated and all within 5 metres of the fumigation site in the grain industry study; therefore, as there was limited data for indoor containers, it was decided that for containers located indoors where there is limited air circulation and the potential for exposure is greater, the recommendations for indoor application sites would be followed, and for containers located outdoors, where any detected phosphine would be expected to dissipate quickly due to mixing with outdoor air, a buffer zone would be established by the certified applicator in consideration of site characteristics and ambient conditions. Similarly, for vessels during the first 24 hours of the fumigation, there were limited samples that were greater than 0.1 ppm in the grain industry study and they were all within 1 metre from the seam of the vessel hatch cover and hold; therefore, it is recommended that a buffer zone be established by the certified applicator provided that additional mitigation measures as specified in the Ship Safety Regulations<sup>1</sup> are also adhered to. For tarpaulins and railcars, there was no information in the grain handling study and limited information in the PPA study; therefore, the 30-metre buffer zone will be maintained. As the air tightness for tarpaulins and railcars are generally low, and the potential for leaks and phosphine levels exceeding the 0.1 ppm exposure limit outside of the fumigation site is expected to be higher than sealed containers, in the absence of any additional data, it was decided to maintain the 30-metre buffer zone.

One of the limitations of the grain industry study was the limited amount of samples taken during aeration. The PPA study did examine aeration in more detail, and the data suggested that during aeration most of the samples that were greater than 0.1 ppm were within 10 metres of the

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<sup>1</sup> see Cargo, Fumigation and Tackle Regulations under the *Canada Shipping Act, current to August 5, 2014*

fumigation site (84%), and were transient in nature as most (99%) occurred within the first 2 hours of aeration. Since there is a greater potential for phosphine levels exceeding the 0.1 ppm level during aeration, it was decided that the certified applicator would be required to be present for the duration of the aeration period (i.e., from the commencement of aeration until the level of phosphine is less than 0.1 ppm in the fumigation site), and that the certified applicator would be required to establish a buffer zone based on their expertise in consideration of site characteristics and ambient conditions and monitor phosphine levels to ensure that workers and bystanders are not exposed to levels of phosphine exceeding 0.1 ppm.

The provisions for difficult-to-evacuate sites (i.e., 200-metre buffer zone), and roads and rights-of-way will be removed, with additional label language and directions added to the fumigation management plan to address these aspects. The data from the grain industry and PPA study did not find any samples greater than 0.1 ppm at distances greater than 130 metres from the fumigation site, with the majority being within 10 metres of the fumigation site. Therefore, the 200-metre buffer zone will be removed and additional wording will be added to the notification section of the Fumigation Management Plan for special consideration of difficult-to-evacuate sites, which may take longer to evacuate. The registrant is also required to develop a Fumigation Management Plan template to better ensure and communicate that monitoring and other conditions of use are conducted according to the existing fumigation management plan.

At the request of the registrant, the term buffer zone will be replaced by fumigation zone. A summary of the fumigation zones required according to site is summarized in Table 1.

**Table 1: Summary of Fumigation Zones According to Site**

Site	Minimum Distance of Fumigation Zone	
	Application and Treatment/Fumigation Period	Aeration/Ventilation Period
Indoor Application Sites	- All workers wear a personal hydrogen phosphide monitor in the facility OR a 10-metre fumigation zone.	Licensed/certified applicator monitors and establishes a fumigation zone.
Vessels	- Fumigation zone determined by licensed/certified applicator.	
Outdoor Application Sites	- Fumigation zone determined by licensed/certified applicator.	
Tarpaulins	- 30-metre fumigation zone OR boundary of the room.	
Railcars	- 30-metre fumigation zone.	

For all sites, periodic monitoring (i.e., monitoring conducted according to a schedule determined by the certified applicator in consideration of site characteristics and ambient conditions) of hydrogen phosphide (phosphine) gas levels at several locations along the fumigation zone perimeter is required. If hydrogen phosphide gas concentrations approach the limit restriction of 0.1 ppm, the applicator must take appropriate action such as extending the fumigation zone.

This requirement continues to ensure that additional protective measures are still in place in the event that there are detections of phosphine level at the fumigation zone perimeter that approach the limit restriction of 0.1 ppm.

### **Chemistry, Environmental, and Value Assessment**

Chemistry, environmental, and value assessments were not required for this application.

### **Conclusion**

The PMRA has reviewed the information available for this application and has determined that amendments to the precautionary statements along with some of the fumigation zones can be supported for the Degesch Phostoxin Tablets label.

## References

<b>PMRA#</b>	<b>Reference</b>
2674638	2016, Analysis of Phosphine Concentrations Measured in Air at Fumigation Sites, DACO: 5.10
2674639	2016, Canadian Grain Industry Phosphine Fumigation Monitoring Study, DACO: 5.10
2674640	2016, Grain Handling Facility Schematic, DACO: 5.10
2674641	2016, Fumigation Monitor Study, DACO: 5.10
2674643	2016, Data Points, DACO: 5.10
2717654	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Readings, DACO: 5.10
2717656	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data and Site Map, DACO: 5.10
2717658	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Readings, DACO: 5.10
2717659	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data 1, DACO: 5.10
2717660	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data 2, DACO: 5.10
2717662	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Readings, DACO: 5.10
2717663	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Readings, DACO: 5.10
2717665	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Site Plan and Data, DACO: 5.10
2717668	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Bin 591, DACO: 5.10
2717669	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Bin 592, DACO: 5.10
2717670	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Bin 593, DACO: 5.10
2717672	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Readings, DACO: 5.10
2717673	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data, DACO: 5.10
2717674	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data, DACO: 5.10
2717676	2016, Canada Grains Council Fumigation Monitoring Study - [Confidential Information Removed] Data, DACO: 5.10

ISSN: 1911-8082

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