



Evaluation Report for Category B, Subcategory 3.4 Application

Application Number: 2016-1373
Application: B.3.4 – Changes to Product Labels – Application Method
Product: Degesch Phosphine Tablets
Registration Number: 15736
Active ingredients (a.i.): Aluminum phosphide
PMRA Document Number : 2641790

Purpose of Application

The purpose of this application was to amend the 50 meter buffer zone on the Degesch Phosphine Tablets label.

Chemistry, Environmental and Value Assessments

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

Health Assessments

Data were submitted and reviewed to amend the 50 meter buffer zone as outlined in the Re-evaluation Decision RVD2015-03, *Aluminum and Magnesium Phosphide and Phosphine Gas*. The submitted data consisted of a summary of air compilation data collected in and around phosphine fumigation sites and a survey characterizing Canadian phosphine fumigation sites.

A blank template spreadsheet and completion instructions were sent to members of the Phosphine Producers Association (PPA) with a request to provide data or to ask their customers to provide data. A total of 14 responses were received, comprising a total of 36 different application sites among the companies reporting. Respondents reported results for 472 fumigation treatments at a variety of standard facilities.

The strength of the current data set is that it provides a total of 4541 spot samples. Out of the 492 samples (10.8%, 492/4541) that were greater than 0.1 ppm (the exposure limit established by the PMRA), the majority were detected inside the fumigation site (22%, 109/492) or adjacent to the fumigation site (42%, 206/492). There were samples greater than 0.1 ppm detected up to 30 meters away from the fumigation site [17% at >1 and ≤ 5 m, 7% > 5 and ≤ 10 m, 4% > 10 and ≤ 20 m, and 0.4% > 20 m and ≤ 30 m]. The current data set suggests that there are no samples greater than 0.1 ppm at distances greater than 30 meters.

As the data submitted is from an observational study, it lacks information that would be captured in a guideline generated protocol study such as having a common limit of detection (LOD) and consistency in sampling between sites (e.g., in terms of sampling times and location, etc.), ensuring all samples consist of replicates, and the inclusion of information on

the type of detection equipment used across all sites. Therefore, while such a study will have limitations, a reduction of the buffer zone from 50 to 30 meters can be supported, based on the weight-of-evidence approach that was used to establish the initial buffer zone of 50 meters.

- The 30 meters is within the range of the downwind fumigation boundaries previously established by the Ministry of Environment in Ontario for structural fumigations (30-40 meters).
- The 30 meters is consistent with the approach in Germany where an initial buffer zone of 10 meters is established for container fumigation that is extended as necessary.
- The 30 meters is larger than the greatest distance of 18 meters where detection of phosphine (70 ppm, tarpaulin fumigation) was found in the previously-submitted Smiley Study (2003).

The weight-of-evidence approach also takes into consideration the strength of the current data submitted to PMRA (i.e., increase in sample size). In addition, as per the RVD2015-03, applicators will still be required to continually monitor hydrogen phosphide (phosphine) gas levels at several locations along the 30 meter 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 requirement continues to ensure that additional protective measures are still in place in the event that there are detects at the 30 meter buffer zone perimeter that approach the limit restriction of 0.1 ppm.

The survey submitted by the PPA suggests that feasibility with a 30 meter buffer zone is expected to increase. However, if there is difficulty in complying with the buffer zones in occupied areas under the control of the owner, roads or right-of-ways, and publicly owned areas; registrants have the option of proposing additional label amendments.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Degesch Phosphine Tablets, and has found the information sufficient to reduce the buffer zone to 30 m on the product label.

References

PMRA Document Number	Reference
2615837	2016. Phosphine Producers Association. Analysis of Phosphine Concentrations from Fumigation Sites. Report Number 1385.001-01. February 25, Unpublished.
2615840	2016. Phosphine Producers Association. Characterization of Canadian Phosphine Fumigation Sites. Report Number 1385.001-02. February 25, 2016. Unpublished.
2615838	2016. Attachment to Analysis of Phosphine Concentration from Fumigant Sites – Air Monitoring Study Spreadsheet. February 25, 2016. Unpublished.
2615842	2016. Attachment to Characterization of Canadian Phosphine Fumigation Sites – Site Characterization Survey Spreadsheet. February 25, 2016. Unpublished.

658374	2003. Phosphine Monitoring Data Collected from Various Types of Fumigation. Report# PPA-2003-1. January 27, 2003. Unpublished. Part 1 of 2.
1048340	2003. Phosphine Monitoring Data Collected from Various Types of Fumigation. Report# PPA-2003-1. January 27, 2003. Unpublished. Part 2 of 2.

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.