



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MEMORANDUM

SUBJECT: Aluminum and Magnesium Phosphide - DCI Requirements

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| Aluminum phosphide | [20859-73-8] | EPA Registry Code # 066501 |
| Magnesium phosphide | [12057-74-8] | EPA Registry Code # 066504 |
| Phosphine | [7803-51-2] | |

Aluminum phosphide and magnesium phosphide are used for fumigation purposes in which the pesticidal activity is due to the phosphine gas that is generated from the parent solid materials. The years of initial registration were 1978 and 1979. In October 1981, registration standards were issued for aluminum and magnesium phosphide. A revised registration standard was issued in October 1986 and the requirements in the revised standard superseded the earlier standard requirements. Both compounds are currently found on List A for Reregistration purposes. A Registration Eligibility Document (RED) was slated to be written for aluminum and magnesium phosphide in fiscal year 1992. However, it has now been determined that the data to support a RED is not complete and RED completion has been postponed.

The current goal of the Phosphine Workgroup is to complete an examination of the data base for aluminum and magnesium phosphide, with particular attention to phosphine itself, and 1) determine if available data are acceptable, and 2) identify additional data needs to be filled by a Data Call-In (DCI). It is projected that a DCI will be issued before the end of FY '92. The Workgroup product(s) are now being forwarded to SRRD with our recommended requirements to assist in the generation of a DCI.

The following requirements as determined by the Phosphine Workgroup are recommended to be included in the DCI for aluminum and magnesium phosphide, with emphasis on testing of phosphine gas. Supporting documents are attached that provide fuller explanations of these requirements.

1) Carcinogenicity: A combined chronic toxicity/carcinogenicity study in rats with inhalation to phosphine gas as the exposure regime is required. Incorporation of a thorough histopathologic analysis of the respiratory tract tissues is required as part of the standard assessment of this assay.

It was decided by the Workgroup and the FIFRA '88 committee meeting (7/23/92) that only one species (rat) would be required at this time. This was due to the major concern for non-food uses. Also, the positive clastogenicity findings are found in the rat after inhalation exposure. This requirement is supported by the concern for exposures in humans of longer than acute duration.

2) Mutagenicity: a) An in vivo/in vitro unscheduled DNA synthesis assay in rat is required to fulfill the other genotoxic effects mutagenicity testing category. Exposure by inhalation to phosphine gas is required.

b) To follow-up the findings of positive clastogenicity in rat lymphocytes and the association of clastogenic events in humans after exposure to phosphine, a test to assess germ cell interaction is also required. An inhalation rat dominant lethal study with phosphine gas is required.

3) 2-Generation Reproduction Study: This study is required in rats and with inhalation exposure to phosphine gas.

4) Neurotoxicity: An acute and 90 day neurotoxicity screening battery is required according to the 1991 guidelines. These tests are required in rat with inhalation to phosphine gas. As a suggestion, a satellite group to the combined chronic toxicity/carcinogenicity study may be added to be used for the 90 day neurotoxicity testing.

5) OREB requests the following requirements:

a) Estimate of product sales by state.
b) Estimate of product use by commodity for each state.
c) Submission of detailed application/product information manual.

d) A detailed discussion addressing risk mitigating techniques available for aluminum and magnesium phosphide. This discussion should address: i) engineering controls available at various sites (if any); ii) application methodologies used with products and population at risk during application/postapplication activities at various use sites; iii) exposure duration per activity, timing and number of applications per season (or year) for different commodities and uses; this should be linked with application and postapplication exposure concerns; iv) ranges and "typical"

application rates for various use scenarios; v) personal protective equipment used and type of clothing worn during handling activities; and, vi) educational training programs available to individuals involved in distribution and use of the product.

6) Residue Chemistry: no new requirements at this time

7) Product Chemistry: no new requirements at this time. However, it is noted that there was an Update of the Residue and Product Chemistry Chapters of the Aluminum and Magnesium Phosphide Registration Standard (5/25/90). The product chemistry update specified numerous data requirements and these are still expected to be fulfilled.