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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: September 21, 2020

SUBJECT: Phosphide (Al and Mg) and Phosphine. Human Health Non-Occupational

Bystander Assessment to Support the Preliminary Interim Decision.

PC Code: Phosphine PC Code: 066500 DP Barcode: D453164

Aluminum Phosphide PC Code: 066501 Magnesium Phosphide PC Code: 066504

Decision No.: 552991 **Registration No.:** Multiple

Petition No.: NA **Regulatory Action:** Registration Review

Risk Assessment Type: Single Case No.:

Chemical/Aggregate

TXR No.: NA

CAS No.: Phosphine: 7803-51-2, Aluminum

Phosphida: 20850 73.8 Magnetical Phosphida.

Phosphide: 20859-73-8, Magnesium Phosphide:

12057-74-8

MRID No.: NA 40 CFR: §180.151

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Risk Management and Implementation Branch II Pesticide Re-Evaluation Division (PRD, 7508P) In support of Registration Review, PRD of the Office of Pesticide Programs (OPP) has requested that HED evaluate the hazard and exposure data and conduct a non-occupational bystander exposure assessment to estimate the risk to human health that will result from the currently registered uses of phosphine and the metal phosphides (aluminum and magnesium). This memorandum serves as HED's draft human health risk assessment of non-occupational bystander exposures from the registered uses of phosphine and the metal phosphides using PERFUM modeling. Qualitative dietary, occupational, and residential exposure; and aggregate assessments from the registered uses of phosphine and the metal phosphides (phosphine/metal phosphides) were all conducted and are detailed in the *Proposed Interim Decision (PID) for Phosphine and the Metal Phosphides*.

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1.0 Background

Phosphine is marketed in several physical forms including metalized solids (aluminum and magnesium phosphide) that emit phosphine after contact with atmospheric moisture through a chemical process and as a cylinderized fumigant containing phosphine. Phosphine is a colorless gas effective against stored-product insect pests and vertebrate pests, mainly rodents, and, in addition to being an active ingredient as cylinderized phosphine, is the active ingredient for the metal phosphides.

The registered formulations of aluminum and magnesium phosphide include pellets/tablets (P/T), gasbags and impregnated materials such as belts. For the registered formulations of phosphine gas, cylinders with varying active ingredient concentrations are used for fumigation purposes. Phosphine may be used as a space fumigant (mills, food plants, warehouses); as a vehicle fumigant (railcars, trucks, vans, containers); as a commodity fumigant (raw agricultural, processed foods, non-food durable goods with bin, chamber, tarp, or other treatment types); as a grain fumigant (silos, farm storage, flat storage); as a vessel or ship fumigant; and for control of burrowing rodents (underground applications, aluminum phosphide).

Exposure Limits

Phosphine is a highly reactive gas and is rapidly taken up via the lungs. All toxicity data submitted to support the aluminum/magnesium phosphide and phosphine registrations were generated for phosphine gas and are by the inhalation route of exposure only. The available data indicate phosphine is highly toxic. Mortality is a common endpoint in the toxicity database following repeated inhalation exposure, and is observed at air concentrations as low as 7.5 ppm.

EPA has not selected points of departure for risk assessment but is relying on various regulatory exposure levels for inhalation exposure to phosphine which exist to protect occupational workers [see Appendix A (Table A1.)]. These include the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL), California OSHA PEL, and the National Institute for Occupational Safety and Health (NIOSH) recommended exposure level (REL), all of which are 0.3 ppm (400 μg/m³) (8-hr TWA). NIOSH and California OSHA have also set a short-term exposure limit (15 minute TWA) for phosphine of 1 ppm (1,390 μg/m³). The American Conference of Governmental Industrial Hygienists (ACGIH) set a threshold limit value (TLV; 8-hour TWA) of 0.05 ppm (71 μg/m³) and a ceiling limit value of 0.15 ppm (210 μg/m³).

1.1 Data Deficiencies

Occupational/Residential Exposure:

• Special Study – Ambient air monitoring. This study is required to assess ambient air concentrations for communities in proximity to treated facilities.

Toxicology:

• Extended one generation reproductive toxicity study. This study is necessary to evaluate effects on parental animals and offspring. The registrant has submitted a waiver using the

special acute inhalation study as support for the extended one generation reproductive toxicity study and is currently under Agency review.

1.2 Label Recommendations

It is recommended to include the following language to address Personal Protective Equipment (PPE) requirements, "Do not wear jewelry, rubber gloves, goggles, tight clothing, rubber protective clothing, or rubber boots when handling. Phosphine can be trapped inside clothing or objects and cause skin injury."

1.3 Pesticide Use Pattern

Use information for phosphine was compiled from review of currently registered product labels and a registrant submission (MRID 50329901, Metal Phosphide and Phosphine Products – Use and Usage Information. S. Nichols, J. Eickhoff, and J. Johnston. 7/13/2017). The information included as part of the registrant submission (MRID 50329901) was compiled from recent industry surveys in 2013 and 2017 as well as a previous report submission (MRID 50095601, Phosphine Concentrations Measured in Air at Fumigation Sites – Report and Analysis, J. Johnston, 10/28/2016).

In the 2013 Scoping Document¹ it was stated that no residential scenarios have been previously quantitatively assessed for phosphine/metal phosphides including for non-occupational bystander exposures. The only residential use is for underground burrowing pest uses of aluminum phosphide in residential areas (recreational areas, athletic fields, golf courses, etc.) with applications only permitted to be made by certified applicators. These residential uses are addressed in the *Proposed Interim Decision for Phosphine and the Metal Phosphides*.

Phosphine/metal phosphide products are registered for the fumigation of a wide range of raw agricultural commodities, processed foods, animal feed and feed ingredients, and non-food commodities (e.g., tobacco, cotton, and wood). Products may also be used to fumigate structures in which no or only residual amounts of commodities are present. Phosphine/metal phosphide products are used at a range of sites and can vary greatly in structure sizes. Representative volumes of structures fumigated with cylinderized phosphine gas or metal phosphides are detailed below:

- Bins, silos, tanks: $5,000 5,000,000 \text{ ft}^3$
- Bunkers, ground piles, flat storage: 100,000 2,000,000 ft³
- Warehouses: Typically, 50,000 1,000,000 ft³; up to 2,600,000 ft³
- Tarpaulin: Typically, 2,000 10,000 ft³; up to 250,000 ft³
- Chambers: Typically, 5,000 50,000 ft³; up to 100,000 ft³
- Railcars: $4,000 6,000 \text{ ft}^3$
- Containers: $1,000 2,700 \text{ ft}^3$
- Trailers: $1,200 5,000 \text{ ft}^3$

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¹ M. King, et. al., D410399, 09/11/2013. Phosphide (Al, Mg) and Phosphine. Human Health Assessment Scoping Document Supporting Registration Review.

• Ship holds: Up to 1,400,000 ft³

• Barges: 80,000 ft³

All phosphine/metal phosphide end-use products are restricted use pesticides due to inhalation toxicity and are only for sale to and for use by Certified Applicators or trained personnel working under the direct supervision of a Certified Applicator. Air monitoring in real-time during fumigations is required and respiratory protection is required when concentrations exceed threshold levels identified on registered labels or are unknown.

Phosphine/metal phosphide products may not be used to fumigate single and multi-family residential properties, nursing homes, schools, daycare facilities, and hospitals. There are no phosphine products registered for homeowner use and no products registered for application to residential areas except for the aluminum phosphide underground uses for burrowing pests.

All fumigation entrances, buffer zones (if applicable), or transport containers fumigated in transit must be placarded with posted warning signs.

For cold storage fumigations, a 30-foot buffer zone must be established from the outside edge of the structure being fumigated unless the structure has been pressure tested and found to be gas tight per USDA testing protocols. Cold storage chambers must be aerated rapidly in order to preserve the quality of the stored commodity. Aeration is not complete until airborne phosphine concentrations are less than the limit value of 0.3 ppm as an 8-hour time weighted average. To ensure bystander safety during rapid aeration of chambers containing fresh commodities fumigated under cold storage conditions, the following buffer zones are currently listed on registered labels:

Volumes Treated	Buffer Zone
$\leq 100,000 \text{ ft}^3$	200 feet
$> 100,000 \text{ ft}^3 \text{ and} \le 500,000 \text{ ft}^3$	350 feet
$> 500,000 \text{ ft}^3$	500 feet

No one is permitted within the buffer zone surrounding the exhaust duct or structure until the structure has aerated for 10 minutes and monitoring indicates that the level of phosphine gas is 0.3 ppm or below.

Current phosphine labels require the development of fumigation management plans, which rely in part on site maps and past history at the site to establish site-specific fumigation boundaries, placarding locations, and other notifications.

See Table 1.3.1 for a summary of representative registered uses of phosphine and metal phosphides.

	Formulation	ve Directions for Use of Phosphine and Application Rate	Hours of	
Commodity	[EPA Reg. No.]	(concentration and mass ai)	Exposure.	Post-fumigation Details
	[Cylinderized Gas Treatmen		<u> </u>
Multiple – maximum rate for all	VaporPH3OS® 99.3% Phosphine Gas (PH3) [68387-8]	200 - 3,625 ppm/1000 ft ³ 1 gram PH ₃ = 25 ppm/1000 ft ³ 1 pound product = 454 grams PH ₃ 3625/25 = 145 grams 145/454 = Max = 0.32 lb ai / 1000 ft ³	24-144 hours	Used in enclosed spaces including cold storage chambers or transport containers, for raw ag commodities, processed foods, stored tobacco, animal feeds, nonfood products. Not for use in barges, or burrow treatments.
commodities listed	Eco2Fume® 2% Phosphine Gas (PH3) [68387-7]	200 - 3,625 ppm/ 1000 ft ³ 16 lb product / 1000 ft ³ Max = 0.32 lb ai / 1000 ft ³	24-144 hours	Used in enclosed spaces including cold storage chambers or transport containers, for raw ag commodities, processed foods, stored tobacco, animal feeds, nonfood products. Not for use in barges, or burrow treatments.
		Aluminum Phosphide Treatn	nents	
Multiple Stored Commodities, Processing Machinery and	GASTOXIN® Fumigation Pellets 57% ai [43743-2]	Maximum Allowable Dosages = 725 pellets or 145 tablets / 1000 ft ³ 145 grams PH ₃ / 1000 ft ³ 0.32 lb ai / 1000 ft ³	Depending on temperature but 48 hour minimum with 8-10 day minimum for colder temps.	For control of insects in stored commodities and burrowing pests. 1 Tablet will release 1 gram PH ₃ . 1 Pellet will release 0.2 grams PH ₃ .
Equipment, and Burrowing Pests	Detia® Fumex Fumigation Bags 57% ai [72959-10]	13 bags / 1000 ft ³ 13 bags * 11 g PH ₃ /bag = 143 grams PH ₃ / 1000 ft ³ 0.32 lb ai / 1000 ft ³	3-14 day minimum depending on temperature	1 - 34 g bag will liberate 11 grams of PH ₃
		Magnesium Phosphide Treatr	nents	
	Degesch Magtoxin® Fumigation Pellets 66% ai [72959-7]	100 grams PH ₃ / 1000 ft ³ 0.22 lb ai / 1000 ft ³	Minimum 34 hours	For spot treatment of food and feed processing machinery and equipment.
Multiple Stored Commodities and Processing Machinery and	Magtoxin® Granules Fumigation Granules only to be used with phosphine Generator 94.6% ai [72959-11]	145 g PH ₃ / 1000 ft ³ 0.32 lb ai / 1000 ft ³	Minimum 2 to 4 days	Only to be used with Degesch Generator. Not to be used to place granules with commodities as other metal phosphide products.
Equipment	Magnaphos® Gas Bags Fumigation Pellets 66% ai [70506-17]	13 bags / 1000 ft ³ 13 bags * 11 g PH ₃ /bag = 143 grams	3-14 day minimum depending on temperature	Bags or tablets, similar products as others listed above.

*Not a comprehensive list of end-use products or label directions.

Personal Protective Equipment: Registered labels list various levels of PPE including, but not limited to, gloves, safety shoes, protective eyewear, and respiratory protection (see list below for respirator type requirements based on exposure condition).

Once phosphine has been introduced into an enclosure, the certified applicator supervising the fumigation must make sure that all persons in the exposure area (the treatment and the buffer zone, if applicable) have appropriate respiratory protection or are removed from the exposure area.

After fumigation, treated areas must be aerated until the level of phosphine is below 0.3 ppm when measured as an 8-hour time weighted average. Re-entry by any person before this time is prohibited unless the appropriate respirator is worn.

No respirator is required if the air concentration level of phosphine in the exposure area is measured below 0.3 ppm as an 8-hour time weighted average. Air monitoring for phosphine is required during the fumigation and aeration periods including handler breathing zone samples to determine when respiratory protection is required.

The following is a list of NIOSH-recommended respiratory protection for workers exposed to phosphine gas:

- When phosphine gas concentrations are between 0.3 3 ppm, the minimum respiratory protection is a supplied-air respirator.
- When phosphine gas concentrations are between 3 and 7.5 ppm, the minimum respiratory protection is a supplied-air respirator operated in continuous-flow mode.
- When phosphine gas concentrations are between 7.5 and 15 ppm, the minimum respiratory protection is a self-contained breathing apparatus (SCBA) with full facepiece or supplied air respirator with a full facepiece, or air-purifying supplied-air respirator (gas mask) with a chin-style front- or back-mounted canister.
- When phosphine gas concentrations are between 15 and 50 ppm, the minimum respiratory protection is a supplied-air respirator equipped with a full facepiece and operated in pressure-demand mode or SCBA with a full facepiece and operated in pressure-demand mode.
- Do not enter areas with phosphine gas concentrations greater than 50 ppm until the phosphine level is reduced to 50 ppm or less.

1.4 Anticipated Exposure Pathways

Humans are not expected to be exposed to phosphine in food, based upon non-detectable residues in magnitude of the residue studies². Exposures through drinking water are not expected since residues are not expected in water due to the use pattern. All phosphine products are Restricted Use Pesticides (RUP) and must be applied by Certified Applicators, so residential handler exposures are not expected. Residential post-application inhalation exposures may occur

² T. Morton, D457813, 6/16/2020, Phosphine: Justification for the Qualitative Dietary Exposure Assessment.

from one aluminum phosphide use which is currently registered for underground treatments for burrowing rodents in residential settings by certified applicators. Burrowing pest treatments must not occur within 100 feet of buildings that are, or may be, occupied by humans or domestic animals and applications made in parks, athletic fields, golf courses, or other areas must be posted and not allow re-entry until 2 days after the final application. Additionally, there is the potential for non-occupational bystander inhalation exposures to phosphine. Occupational dermal exposures to phosphine are not expected given the high vapor pressure and based on the labeled delivery systems. Occupational inhalation exposures are possible. Occupational handlers may be exposed during all phases of the application process including after application and during clearance procedures and tarp removal (if applicable). Occupational post-application workers may be exposed while performing activities associated with commodities previously treated with phosphine.

A spray drift assessment was not completed for phosphine. The application practices for phosphine/metal phosphides are not reflected in the standard spray drift assessment as outlined in the Residential SOP Addenda 1: *Consideration of Spray Drift*³. The commodity uses of phosphine/metal phosphides are not expected to result in spray drift because applications typically occur inside or under tarps and the method of application is as a pressurized liquid directly applied from a cylinder or drum which comes out in gaseous form (i.e., creates no aerosols) or as tablets/pellets, bags, and/or strips placed inside of structures/containers. Therefore, spray drift exposures have not been quantitatively assessed.

2.0 Non-Occupational Inhalation Exposure Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency has developed a Volatilization Screening Tool and a Volatilization Screening Analysis⁴ for conventional pesticides. However, unlike most conventional pesticides, the Screening Analysis is not applicable to phosphine because of the extensive information available on its use patterns and physiochemical properties (e.g., vapor pressure). Bystanders who live or work near commodity fumigation sites are potentially exposed to fumigant emissions that travel off-site. Potential bystander exposures have been modeled as detailed below. There is also the potential for inhalation exposure to phosphine via ambient air resulting from multiple commodity applications across airsheds from multiple sources and are not meant to represent exposures associated with a single application event but could represent potential exposures of communities near phosphine use.

2.1 Non-Occupational Bystander Post-Application Inhalation Exposure Estimates

Bystanders who live or work near sites where commodity fumigation occurs are potentially exposed to fumigant emissions that travel off-site.

For Registration Review, the Probabilistic Exposure and Risk Model for Fumigants (PERFUM) was used for the quantitative non-occupational bystander exposure assessment using the latest

³ https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0676-0003

⁴ <u>https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2014-0219-0003&disposition=attachment&contentType=pdf</u>

version of the model, PERFUM 3.0. This PERFUM analysis has taken into account the variety of fumigations described in the currently registered end-use product labels for phosphine/metal phosphides. This includes any specific emission release heights and ventilation rates noted on the labels, as well as generic values (detailed below) for when those inputs are not specified on the label. PERFUM was used in the phosphine assessment to model air concentrations from emissions around fumigation facilities that could be compared to regulatory or recommended exposure limit values.

During Registration Review, HED has noted that label required buffer zones are identified for the cylinderized phosphine gas treatments in chambers containing fresh commodities fumigated under cold storage conditions. Label required buffer zones prohibit entry into the buffer zone surrounding the exhaust duct outlet or structure until the structure has aerated for 10 minutes and monitoring indicates that the level of phosphine gas is 0.3 ppm or below. The following buffer zone distances are identified on those labels:

- 200-foot buffer for all aeration methods and fumigations \leq 100,000 ft³
- 350-foot buffer for all aeration methods and fumigations $>100,000 \text{ ft}^3$ and $\leq 500,000 \text{ ft}^3$
- 500-foot buffer for all aeration methods and fumigations > 500,000 ft³

PERFUM Inputs:

Meteorological Data: Phosphine/metal phosphide products are used at a wide range of sites. Typically for fumigants, major commodity uses occur in the coastal regions of Florida and California at ports, and significant levels of commodity production also occur in these coastal regions; therefore, data from these locations were considered. Meteorological data representing these regions were used in this assessment, and specifically included Ventura, California, and Bradenton, Florida. These two locations also generally resulted in the highest modeled air concentration levels of all potential meteorological sites across all fumigants.

Treatment Types & Exposure Scenarios: A series of scenarios have been completed in order to assess the exposure profiles associated with the commodity uses of phosphine/metal phosphides. These factors stipulate the nature of the buildings, chambers, or structures being treated; application rates and treatment durations; and emission rates and factors. The various types of treatment scenarios include:

- Vacuum-sealed Chamber or other Enclosed Structures During Treatment: This scenario represents concentrations resulting from potential leaks from a chamber or structure during treatment (also referred to as a fugitive emission) where the desire is to retain phosphine according to the *CxT* (concentration x time) schedules until a desired level of efficacy is reached.
- Aeration with No Stack: This scenario represents concentrations that are emitted from a chamber or structure after treatment is complete and the desire is to remove remaining phosphine as quickly as possible. Different aeration scenarios have been assessed representing phosphine being purposely vented, with a range of air exchange rates, but there is no stack available to transport emissions further up into the atmosphere. A

passive aeration scenario representative of practices such as a door being opened for aeration, is also presented. This latter scenario is assumed to be representative of a truck/trailer, railcar, tent or tarped commodity, and transport container fumigations. The release heights for the treatment, no-stack, and passive aeration scenarios are half the height of the building.

- Aeration with Vertical Stack: This scenario represents concentrations that are emitted from a chamber or structure after treatment is complete and the desire is to purposely vent remaining phosphine as quickly as possible through a vertical stack. In this scenario, phosphine is purposely vented through a stack to transport emissions further up into the atmosphere to reduce buffer distances and enhance dilution. The results are reflective of a warehouse or other structure that is treated and a stack (of varying heights) is on the roof for ventilation purposes. For all point source models, the impacts of near building downwash effects are accounted for as PERFUM will call the Building Profile Input Program (BPIP source code provided on U.S. EPA website and compiled in PERFUM) to calculate downwash parameters, if necessary.
- Aeration with Portable Vertical Stack Not Near Building: This scenario represents a situation where phosphine is vented through portable tubing to a stack in an area adjacent to a treated structure or chamber. The scenario represents concentrations that are emitted from a chamber after treatment is complete and the desire is to purposely vent remaining phosphine as quickly as possible. In this scenario, phosphine is purposely vented through a stack to transport emissions further up into the atmosphere to reduce buffer distances and enhance dilution. The results reflect a warehouse or other structure that is treated and phosphine is transported through a portable stack, typically within 200 feet of the facility for ventilation purposes. The near building downwash effects are minimized because of the placement of the stacks away from the building/structure in this scenario.
- Aeration with Mobile Ground Level Source Not Near Building (horizontal stack): This scenario represents a situation where phosphine is vented through portable tubing where the output tube is laid on the ground in an area adjacent to a treated structure or chamber. The scenario represents concentrations that are emitted from a chamber after treatment is complete and the desire is to purposely vent remaining phosphine as quickly as possible. In this scenario, phosphine is purposely vented through the tubing to transport emissions away from the chamber or facility to reduce buffer distances. The results reflect a warehouse or other structure that is treated and then phosphine is transported through tubing with the output typically within 200 feet of the facility for ventilation purposes.

Source Term Determination:

- The emission flux calculations were based on whether the source should be considered as an area source or a point source.
- All treatment and aeration no-stack scenarios were modeled as area sources which assume leakage or aeration evenly across an entire structure with a release height of half the height of the building.

• All aerations performed with a stack were modeled as point sources which assumes all emissions are through a single stack, or as a structure with several point sources located at varied points across a structure (see *stack diameters* below).

Treatment Concentrations (maximum concentrations derived from labels):

• The maximum fumigation rate which was identified on end-use products for each of the metal phosphides and phosphine: 0.32 lb phosphine/1000 ft³, resulting in a maximum concentration of 3,625 ppm (see Table 1.3.1).

In addition to modeling the treatment application concentration noted above, the PERFUM outputs also include air concentrations at various distances based on a percentage of the modeled application rate (from 1% to 100%).

Structure Volume:

- All structures: 1,000, 2,000, 5,000, 10,000, 25,000, 50,000, 100,000, 250,000, 500,000, 750,000, 1,000,000, 2,500,000, 5,000,000, 7,500,000, and 10,000,000 ft³.
- For truck/trailer and air/sea transport container fumigations, it is assumed that the 2,000 ft³ and 5,000 ft³ building scenarios would represent these types of fumigations. For trailer lengths of 40 53 ft, volumes range from approximately 2,400 ft³ to 3,500 ft³. For typical 20- and 40-foot sea transport containers, volumes range from approximately 1,100 ft³ to 3,100 ft³.
- For railcar fumigations, it is assumed that the 5,000 ft³ and 10,000 ft³ building scenarios would represent this type of fumigation. Typical rail cars range in length from 50 to 86 feet with volumes ranging from approximately 5,200 ft³ to 10,000 ft³.

Chamber/Structure Height:

- $1,000 \text{ ft}^3 = 10 \text{ ft tall}$
- $2.000 \text{ ft}^3 = 12 \text{ ft tall}$
- $5,000 \text{ ft}^3 = 17 \text{ ft tall}$
- $10,000 \text{ ft}^3$, $25,000 \text{ ft}^3$, and $50,000 \text{ ft}^3 = 25 \text{ ft tall}$
- $100,000 \text{ ft}^3$, $250,000 \text{ ft}^3$, $500,000 \text{ ft}^3$, $750,000 \text{ ft}^3$, and $1,000,000 \text{ ft}^3 = 75 \text{ ft tall}$
- $2,500,000 \text{ ft}^3$, $5,000,000 \text{ ft}^3$, $7,500,000 \text{ ft}^3$, and $10,000,000 \text{ ft}^3 = 100 \text{ ft tall}$

Stack & Release Heights:

- All fixed stack heights = 10, 25 and 50 feet above roof of chambers or structures [Note absolute release height (i.e., the height at which release is occurring or building height plus stack height) then varies when added with specific building height]
- Portable stack heights = 5, 10, 25, and 50 feet
- Horizontal stack height = 3 feet

⁵ https://cerasis.com/wp-content/uploads/2015/08/2015TrailerGuide.pdf

⁶ https://www.icontainers.com/the-different-types-of-containers/

⁷ https://www.csx.com/index.cfm/customers/resources/equipment/railroad-equipment/

Active Air Exchange Rates:

Per the registered cylinderized phosphine gas labels for cold storage chambers, exhaust equipment capable of replacing the air in the chamber with fresh air in about 1 or 2 hours must be used. All other aerations not for cold storage chambers, do not identify a minimum or maximum air exchange rate but state that for fresh fruits and vegetables it is necessary to aerate commodities for a minimum of 48 hours prior to offering them to the end consumer. For these fumigations where the labels do not provide specific requirements, a range of air exchanges were modeled including 0.1, 0.2, 0.5, 1, 2, 5, 10, 20, and 50 air exchanges per hour. Additionally, treatment and passive aeration for all fumigation scenarios were modeled using a default air exchange rate of 0.05 hr⁻¹.

Stack Diameters:

PERFUM can only accommodate a single stack so the diameters are varied in order to achieve the proper cross-sectional ventilation areas for each combination of chamber/structure size and air exchange value. The results for larger chambers or high concentration treatments, therefore, may be based on very large diameter stacks which would not occur in reality to achieve proper ventilation (i.e., 0.2 m to 5 m). Under actual conditions, multiple stacks would be used in order to achieve target air exchange rates. The architecture of PERFUM requires that these analyses be done in this manner. This approach is not expected to be a negative bias in the results. In fact, this approach is likely a conservative method because all emitted phosphine is forced out at one location making the predicted distances higher.

Treatment Frequency & Emission Profiles:

Based on label directions for length of treatments and aerations (presented in Table 1.3.1), different exposure durations were modeled including 8- and 24-hour intervals. The duration of the treatment cycle depends on the commodity, temperature, and the nature of the fumigation to include maximum treatment durations between 24 and 144 hours for the cylinderized phosphine gas products and up to 14 days for the metal phosphide bag products. The 24-hour emission profile can be modeled as three 8-hour averaging periods which closely matches the regulatory and recommended exposure limits which are based on 8-hour time-weighted averages (TWAs). Model runs were extended to 5 days in length to simulate the longer fumigation and aeration treatment cycle durations in 8 or 24 hour increments. The Agency previously concluded that a box-type exponential emissions model is the appropriate approach for developing emission terms for modeling flux which has been used as the basis for all calculations.

A variety of emission types and scenarios were considered in this assessment for comparison purposes and to simulate specialized situations. The first situation is meant to represent a single fumigation treatment and aeration event. In certain cases, multiple emissions were also evaluated to simulate situations where multiple sequential treatments (e.g., new treatment every hour for 8 hours) are conducted and aerated in sequence (not applicable to the larger structure sizes). A situation was also modeled that involved a possible catastrophic breach of a containment where the treated mass is totally released in one hour to simulate such an event.

Target Concentrations:

The target concentrations that the phosphine PERFUM modeling was compared to are the various regulatory and recommended exposure limits detailed in Table A.1.

PERFUM Output:

PERFUM calculates outputs based on each day's worth of meteorological data and the result is illustrated by Figure 1 which shows the distances from the commodity facility (i.e., chamber or building, green square) where airborne concentrations meet a threshold of concern around its perimeter (i.e., the irregularly shaped red line). The solid black concentric circle represents an example 95th percentile distance value around the perimeter (i.e., the distance for that day where MOEs are not of concern for 95% of those exposed). The cross-hatch area represents the locations where distances exceed the 95th percentile value (i.e., risks are of concern at these distances which represent 5% of the exposed population).

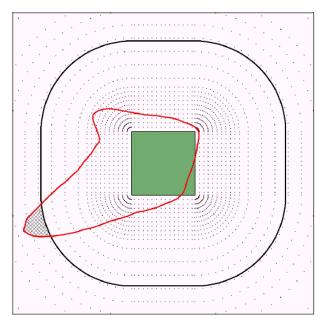


Figure 1: Example Daily PERFUM Output

PERFUM generates output for each day over a 5-year period (i.e., 1825 days) then summarizes the information by providing two types of results that include the "Maximum Buffer" distance and the "Whole Field Buffer" distance. Each is reported as a distribution.

The "Maximum Buffer" distribution is based on the maximum distance needed in order for the modeled air concentrations calculated using PERFUM for each day to not be of concern (i.e., modeled air concentration is less than the target concentration adjusted by the uncertainty factor) (i.e., a distribution of the farthest single points on the irregular red line from Figure 1 for each day). This results in a distribution that contains 1825 values.

The "Whole Field Buffer" is also based on values from each day, except the distances on which the distribution is based include the points where the entire irregularly shaped red line cross the spokes coming out from each building, not just the farthest point on the line from Figure 1. The number of values in the distributions vary and are based on 1825 days (or more intervals if averaging time is less than 24 hours) multiplied by the number of spokes around the building which relates to the building footprint.

For phosphine, the modeled air concentrations were not directly compared to a target concentration as no target concentration was selected. Instead the air concentrations will be directly compared to the regulatory or recommended exposure limit values described in Appendix A, Table A.1.

PERFUM Results:

Treatment scenarios: In addition to considering appropriate buffer distances and other mitigation strategies during the aeration phase in commodity treatments, it is also important to consider how much material may leak from a chamber (or truck/trailer) during the treatment phase. In order to simulate this, low percentage mass release values (1% and 10% mass released) were used to mimic such situations. These estimates were calculated based on a passive aeration scenario assuming this would essentially represent a leaky box which is what would be expected during treatment in most situations. Table 9.1.1 provides a summary of the results for fumigation scenarios and show that, in all cases, air concentrations at any distance from the application site are below any regulatory or recommended exposure limit (400 μ g/m³ and 71 μ g/m³, respectively).

HED notes that these scenarios have been modeled at the maximum treatment application rate identified on the registered labels of 0.32 lb ai/1,000 ft³.

Table 9.1.1. PERFUM Phosphine Concentrations (μg/m³) During <u>Fumigation Treatment (0.32 lb ai/1,000 ft³)</u> for Varied										
Structure Sizes & Varied Percent Mass Released (1% and 10%), Using Bradenton, FL Weather Data. Building Size \rightarrow 2,000 ft ³ 5,000 ft ³ 10,000 ft ³ 100,000 ft ³ 250,000 ft ³										
	1%	10%	1%	10%	1%	10%	1%	10%	1%	10%
Percentiles ↓	Released	Released	Released	Released	Released	Released	Released	Released	Released	Released
	S*/M*	S/M	S/M	S/M	S/M	S/M	S/M	S/M	S/M	S/M
	Phosphine Air Concentrations (μg/m³)*									
90	0.77/2.9	7.7/29	0.22/0.97	2.2/9.7	0.1/0.49	1/4.9	0.045/0.022	0.45/0.22	0.12/0.54	1.2/5.4
95	0.97/3.7	9.7/37	0.29/1.3	2.9/13	0.14/0.66	1.4/6.6	0.063/0.032	0.63/0.32	0.16/0.77	1.6/7.7
99	1.3/5.1	13/51	0.43/1.8	4.3/18	0.21/0.91	2.1/9.1	0.099/0.048	0.99/0.48	0.24/1.2	2.4/12

*S = single fumigation, M = multiple sequential fumigations. Maximum air concentration at any distance reported on day 1. OSHA PEL = $400 \mu g/m^3$, ACGIH TLV = $71 \mu g/m^3$.

Aeration Scenarios: After treatments are complete, the objective is to aerate as quickly as possible, but the mass being aerated depends upon how well the chamber worked at retaining phosphine and how much phosphine was potentially absorbed by the commodity and/or packaging. There is likely a range for the mass aerated, with a more conservative assumption being that approximately 99% of the administered phosphine is available at the beginning of aeration, but it's likely to be lower. Therefore, assumptions of 75% and 95% of the administered phosphine available at the beginning of aeration could also be considered. Due to issues with the modeling software, the mass release presented is 100% of the administered phosphine which likely results in an overestimate of actual phosphine concentrations.

Tables 9.1.2 and 9.1.3 provide examples for passively aerated fumigations of various structure sizes, showing the modeled phosphine air concentrations assuming 100% mass released. As noted above, the 2,000 ft³, 5,000 ft³, and 10,000 ft³ structure size scenarios are assumed to be most representative of truck/trailer, air and sea transport container, and railcar fumigations. Depending on the percentile selected and application parameters, air concentrations at varied

distances from the application site may be greater than the regulatory or recommended exposure limits (400 μ g/m³ and 71 μ g/m³, respectively).

Table 9.1.2. PERFUM Phosphine Concentrations (μg/m³) During Fumigation Passive Aeration (0.32 lb ai/1,000 ft³) for Varied								
Structure Sizes, 100	Structure Sizes, 100% Mass Released, No Stack, and 0.05 hr ⁻¹ Air Exchange Rate Using Bradenton, FL Weather Data.							
Building Size →	2,000 ft ³	5,000 ft ³	10,000 ft ³	25,000 ft ³	50,000 ft ³	100,000 ft ³		
Building Size →	S*/M*	S/M	S/M	S/M	S/M	S/M		
	Phosphine Air Concentrations (μg/m³) ¹							
90	77/290	22/97	10/49	25/120	47/210	4.5/22		
95	97/370	29/130	14/66	33/150	62/280	6.3/32		
99	130/520	43/180	21/91	50/210	93/390	9.9/48		
Distance (meters) ²	1	5	15	15	15	100		

^{*}S = single fumigation, M = multiple sequential fumigations. OSHA PEL = $400 \mu g/m^3$, ACGIH TLV = $71 \mu g/m^3$.

^{2.} Modeled distance at which the maximum concentration was observed.

Table 9.1.3. PERFUM Phosphine Concentrations (μg/m³) During <u>Fumigation Passive Aeration (0.32 lb ai/1,000 ft³)</u> for Varied Structure Sizes, 100% Mass Released, No Stack, and 0.05 hr¹ Air Exchange Rate Using Bradenton, FL Weather Data.								
Duilding Cine	2500006^3 5000006^3 10000006^3 25000006^3 50000006^3 100000006^3							
Building Size →	S*/M*	S	S	S	S	S		
	Phosphine Air Concentrations (µg/m³) ¹							
90	12/54	24	49	61	120	220		
95	16/78	33	62	84	160	290		
99	24/120	48	94	120	220	390		
Distance (meters) ²	50	50	50	100	50	50		

^{*}S = single fumigation, M = multiple sequential fumigations. Multiple scenarios not anticipated for very large structures. OSHA PEL = $400 \mu g/m^3$, ACGIH TLV = $71 \mu g/m^3$.

Tables 9.1.4 and 9.1.5 provide examples for aerated fumigations of various structure sizes, utilizing a 10-foot stack, with 2 air changes per hour, showing the modeled phosphine air concentrations assuming 100% mass released.

Table 9.1.4. PERFUM Phosphine Concentrations (μg/m³) During <u>Fumigation Aeration (0.32 lb ai/1,000 ft³)</u> for Varied Structure								
Sizes, 100% Mass R	Sizes, 100% Mass Released, 10-foot Stack Heights, and 2 Air Changes per Hour Using Bradenton, FL Weather Data.							
Building Size →	2,000 ft ³	5,000 ft ³	10,000 ft ³	25,000 ft ³	50,000 ft ³	100,000 ft ³		
Building Size →	S*/M*	S/M	S/M	S/M	S/M	S/M		
	Phosphine Air Concentrations (µg/m³) ¹							
90	1.4/7.7	1.9/11	3/18	6.3/38	35/190	2.9/21		
95	2.4/10	3.5/15	5.7/24	12/51	58/260	6.7/30		
99 3.9/14 5.3/21 8.6/34 18/73 80/370 13/44								
Distance (meters) ²	25	50	50	50	25	100-150		

^{*}S = single fumigation, M = multiple sequential fumigations. OSHA PEL = $400 \mu g/m^3$, ACGIH TLV = $71 \mu g/m^3$.

^{1.} Maximum air concentration at any distance reported on day 1.

^{1.} Maximum air concentration at any distance reported on day 1.

^{2.} Modeled distance at which the maximum concentration was observed.

^{1.} Maximum air concentration at any distance reported on day 1.

^{2.} Modeled distance at which the maximum concentration was observed.

Table 9.1.5. PERFUM Phosphine Concentrations (μg/m³) During <u>Fumigation Aeration (0.32 lb ai/1,000 ft³)</u> for Varied Structure Sizes, 100% Mass Released, 10-foot Stack Heights, and 2 Air Changes per Hour Using Bradenton, FL Weather Data.							
Sizes, 100% Mass B	keleased, 10-foot Sta	ick Heights, and 2 A			FL Weather Da		
Building Size →	250,000 ft ³	500,000 ft ³	1,000,000 ft ³	2,500,000 ft ³	5,000,000 ft ³	10,000,000 ft ³	
Building Size →	S*/M*	S	S	S	S	S	
		Phosphine A	ir Concentrations (μg/n	n ³) ¹			
90	5.6/43	33	44	290	200	1,600	
95	13/60	67	96	610	460	3,000	
99	24/89	110	150	1,000	800	4,800	
Distance at which phosphine concentration decreases below OSHA PEL (90 th percentile) (meters) ²	NA	NA	NA	NA	NA	150	

*S = single fumigation, M = multiple sequential fumigations. Multiple scenarios not anticipated for very large structures. OSHA PEL = $400 \mu g/m^3$, ACGIH TLV = $71 \mu g/m^3$.

It is clear that given the number of possible permutations of PERFUM inputs and ways of presenting the outputs that there are many possible approaches for interpreting the results. The central goal, however, is to quantify how potential exposure profiles change with changes in various input factors. Based on the range of input parameters that have been considered in this analysis and the various outputs that are available, some general conclusions can be drawn with regard to the trends observed in the results including:

- As shown in Table 9.1.1, modeled phosphine concentrations during fumigation treatments are relatively low, noting that all concentrations are less than the regulatory and/or recommended exposure limit values detailed in Appendix A, Table A.1.
- For the various fumigation aeration configurations presented in Tables 9.1.2 through 9.1.5, the modeled phosphine concentration can vary ranging from 1.4 to 4,800 μg/m³ across the reported percentiles. The modeled concentrations increase about 4 times with the sequential multiple fumigation pattern compared to a single fumigation. Further information on typical stack heights and air exchange rates would result in more refined modeled phosphine concentrations. The modeled aeration scenarios result in the majority of phosphine concentrations being below the OSHA PEL with a few exceptions for the larger structure sizes. Preliminary review of the aeration scenarios presented above results in phosphine concentrations reaching levels below the OSHA PEL regulatory limit of 400 ug/m³ at a distance of 300 meters or less from the fumigation source. For most cases, the cold storage buffer zones listed on the currently registered labels would be protective of the PERFUM modeled results.
- There does not appear to be a significant difference in buffer distances between the two geographic locations modeled (CA vs FL). Assessment results were presented using Bradenton, FL meteorological data in this document. Review of the different output files indicates that depending on the fumigation scenarios, modeled buffer distances will fluctuate between the two meteorological site data. However, it does not appear that use of a particular source of weather data impacts the general trends in the results.
- The following trends generally hold true but not in every instance:

^{1.} Maximum air concentration at any distance reported on day 1.

^{2.} Modeled distance at which the phosphine concentration decreases below the OSHA PEL for the 90th percentile.

- Modeled phosphine concentrations were higher for the larger building sizes (except in some instances where the lower building volumes also correlated to lower release heights) and at the higher percentiles of exposure.
- o For portable and fixed stacks, higher stack heights resulted in the largest decrease in the modeled phosphine concentrations.
- It was also noted for portable and fixed stacks, higher air exchange rates usually resulted in smaller modeled phosphine concentrations but not in all cases and it did not impact results as much as higher release heights.

In conclusion, it is clear that many different factors can impact the air concentrations, and resulting exposure profiles, in proximity to fumigation facilities/sites that are used for treatments with phosphine; these include many of the factors which have been identified above. It is also important to acknowledge this issue so that stakeholders understand that the results of this analysis can be interpreted in many ways depending upon the factors which are considered. Many conclusions can be drawn, but the key ones include: (1) there does not appear to be a significant difference in the phosphine concentrations when using CA meteorological data versus FL meteorological data; (2) release heights (i.e., stack heights) seem to impact the modeled buffer distances the most significantly with higher release heights resulting in smaller predicted buffer distances; (3) larger building sizes tend to result in larger predicted buffer distances (except for some instances where the release height is lower for the lower building volumes resulting in higher modeled buffer distances), and (4) higher air exchange rates usually resulted in smaller modeled phosphine concentrations but not in all cases and it did not impact results as much as higher release heights.

2.2 Additional Non-Occupational Bystander Air Concentration Data

Air Monitoring Data Submitted by the Phosphine Producers Association (PPA):

The Phosphine Producers Association (PPA) sponsored the collection and reporting of a compilation of air monitoring concentrations measured in and around phosphine fumigation sites collected during 2015 and 2016. The collected air data were compiled into a database and included over 6,200 valid data rows that represent 575 fumigation treatments conducted at multiple locations in Canada, the United States, and Chile. Fumigations in six broad categories (bin, chamber, container, ship, structure, and tarp) and all three active ingredients (aluminum phosphide, magnesium phosphide, and phosphine gas) are represented in the database. A range of application rates and treatment volumes as well as measurements made at various times (e.g., during treatment hold periods, during aeration, and post-fumigation) and locations in and around fumigation sites are represented. Most of the samples are direct read phosphine concentration measurements representing very short-term exposures but also include applicator breathing zone time weighted average samples.

The database contains 4,332 measurements that address potential exposures to unprotected workers or non-occupational bystanders. Of these, 1,426 were made during treatment hold periods, 2,812 were made during aeration, and 94 were made post-fumigation and include measurements at distances ranging from 1 to 305 meters from the fumigation site. The phosphine

air monitoring database compiled by PPA is large and robust, and it reflects the diversity of phosphine fumigations.

After review and analysis of the air monitoring data submitted by the PPA, a heat map of air concentrations by distance was created, see Figures 2 and 3. The heat map compared air concentrations against the OSHA permissible exposure limit (PEL) and NIOSH REL of 0.3 ppm, as a time-weighted average (TWA) and the NIOSH short-term exposure limit (STEL) value of 1.0 ppm (see Appendix A, Table A.1).

- O About 85% of the 6,143 usable samples submitted by the PPA were below the LOD (LODs range from 0.01 ppm to 0.3 ppm).
- Of 6,143 samples, 1,811 of them were taken inside the enclosed/placarded area of the fumigation, inside the treatment area, or as an occupational personal breathing zone sample, making these samples irrelevant for non-occupational bystander exposures.
- The remaining 4,332 samples were binned by concentration and distance from the fumigant source.
 - 4,286 (~99%) of these samples resulted in concentrations less than the OSHA PEL of 0.3 ppm.
 - 34 of the remaining 46 samples (<0.1% of the total) measured between 0.3 ppm and 1 ppm. 12 of these 34 samples were taken inside of 10 feet and another 20 were collected between 10 and 30 feet from the fumigation area. Three samples noted issues with faulty door seals.
 - 5 of the 20 samples, all collected from a seed warehouse structure treatment with aluminum phosphide of 2.4 million cubic feet, about 30 feet from the fumigation area, range from 0.32 ppm to 0.72 ppm.
 - The remaining 12 of the 46 samples (<0.1% of the total) measured equal to or greater than 1 ppm and 11 of these samples were taken inside of 15 feet from the fumigation area. Also 6 samples noted issues with faulty door seals, fan seals, or a cracked foundation.
 - The 1 remaining sample measured at 5 ppm from a pasta warehouse fumigation in Canada with an LOD of 0.1 ppm.

Phosphine Air Monitoring Data Binned
by Concentration and Distance

Samples <0.3 ppm Samples >0.3 <1.0 ppm Samples >1.0 ppm

100%

100 Feet

10 to 30 Feet

30 to 100 Feet

Figure 2 – Data Gradient Across Distances Focused on Higher Concentration Distribution

^{*}All samples greater 0.3 ppm represent 46 of the 4,332 individual sample measurements.

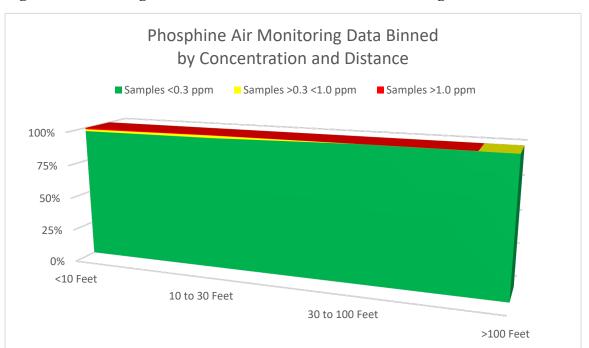


Figure 3 – Percentage of Data Points within Concentration Ranges Across Distances

^{*}All samples greater 0.3 ppm represent 46 of the 4,332 individual sample measurements.

Air Monitoring Data Identified from California DPR Air Resources Board (ARB):

In the 2013 scoping document for registration review, 8 ambient air monitoring was required to assess ambient air concentrations for communities in proximity to treatment facilities (SS-1076). Ambient air exposures to phosphine can be acute as well as longer-term in nature. Although ambient air data were required for phosphine, no ambient air data were submitted. A publicly available air monitoring report for phosphine 9 was identified from the California DPR ARB database. The air monitoring data identified more closely represents a non-occupational bystander exposure and not true ambient air exposures, therefore the previously required ambient air monitoring study is still outstanding.

The ARB monitored one application site for phosphine which was performed prior to, during, and after the use of phosphine as a post-harvest commodity fumigant on almonds. The location was a commercial commodity fumigation facility located in Merced County, CA. The fumigation was performed by placing a measured quantity of aluminum phosphide pellets (2500 pellets or 3 kg total) inside a large chamber (about 25,000 ft³) and allowing for the generation of phosphine gas with a 31-foot exhaust stack used for aeration. Fumigation lasted almost 6 days due to low ambient temperatures. Aeration time was not recorded in report but samples were collected over 12 hours after the fumigation period concluded.

A total of 75 samples (62 application samples and 13 field quality control samples) were collected from 8 samplers located 15 to 40 feet from the exterior walls of the fumigation chamber. Twenty-two hour samples were collected before fumigation began, 4-hour samples were collected during the active fumigation, and 4-hour samples were collected during the aeration phase of the treatment. The laboratory established a method detection limit (MDL) of $0.743 \, \mu \text{g/m}^3$ and an estimated quantitation limit (EQL) of $3.715 \, \mu \text{g/m}^3$.

All background period ambient samples collected prior to fumigation initiation were reported at less than the MDL indicating very low levels of phosphine is present when fumigations are not actively being conducted at this location. Ambient samples during the fumigation period ranged from less than 1 $\mu g/m^3$ to 58.33 $\mu g/m^3$ and the samples taken during the aeration phase were reported from less than 1 $\mu g/m^3$ to 6 $\mu g/m^3$ (an analysis of the raw data was not conducted; values as reported were used).

All the samples collected during all periods of the fumigation process resulted in air concentrations below the regulatory and recommended OSHA PEL, NIOSH REL and ST, and ACGIH TLV and Ceiling exposure limits as detailed in Appendix A.

EPA National Air Toxics Assessment (NATA) 10:

In August 2018, EPA released the most recent update to the National Air Toxics Assessment (NATA). NATA is EPA's ongoing review of air toxics in the United States, and was developed as a screening tool for state, local, and tribal air agencies. NATA's results help these agencies

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⁸ M. King, et. al., D410399, 09/11/2013. Phosphide (Al, Mg) and Phosphine. Human Health Assessment Scoping Document Supporting Registration Review.

⁹ California Air Resources Board, N. Adler, 06/07/2010. Report on Air Monitoring of the Application of Phosphine in Merced County in December 2008

¹⁰ https://www.epa.gov/national-air-toxics-assessment

identify which pollutants, emissions sources, and places they may wish to study further to better understand any possible risks to public health from air toxics. These data aren't intended to provide precise exposures and risks for a specific person, and are best applied to larger areas (counties, states, and the nation as a whole).

The Agency based the emissions used in the NATA assessment on the 2014 National Emissions Inventory (NEI) which reflects various emission source types including point sources, non-point sources, mobile sources, fires, and biogenic sources. Using the NEI data paired with two models (CMAQ and AERMOD) the Agency estimated ambient concentrations of air toxics across the United States. The Agency modeled all NATA pollutants using AERMOD which provides ambient air concentrations for each receptor which were used to calculate census tract-level concentrations. More information about these models and the process for generating ambient concentration data may be found in Section 3 of the 2014 NATA: Technical Support Document.¹¹

The most recent NATA 12 uses emission data from 2014 to estimate health risks from toxic air pollutants. After review of the NATA data for phosphine, the highest modeled ambient annual average air concentration identified in any region of the U.S. was 0.0019 mg/m^3 which is less than the regulatory or recommended OSHA PEL/NIOSH REL level of 0.4 mg/m^3 and the ACGIH TLV level of 0.071 mg/m^3 (0.05 ppm).

Human Incident and Epidemiology

The previous incident report (S. Recore and E. Evans, D411384, 5/8/2013) concluded that magnesium phosphide and phosphine had a relatively low frequency and severity of incident cases reported in both IDS and NIOSH SENSOR-Pesticides and there was no apparent concern that would warrant further investigation. For aluminum phosphide, in IDS there was a low frequency of incidents but one incident resulted in two deaths. In NIOSH SENSOR-Pesticides there was a moderately high frequency of incidents that were mostly moderate or low in severity. In 2010, EPA and the primary manufacturers of aluminum and magnesium phosphide pesticide products expanded and clarified the outdoor use restrictions for all phosphine product uses against burrowing rodents.

An updated incident report and epidemiology review (E. Evans, S. Recore, and E. Jones, D453165, 7/31/2019) was generated for registration review and confirmed that aluminum phosphide was involved in more incidents than phosphine and magnesium phosphide combined. Aluminum phosphide incidents reported in IDS ranged from major to minor severity, with five incidents resulting in fatalities. Two of the fatalities were due to illegal use of the product in a residential home, two were due to ingestion of the product to self-harm, and one had no exposure details. The two incidents reported for phosphine and magnesium phosphide in the IDS were of moderate severity. A majority of the phosphine/fumigant metal phosphide incidents reported in the SENSOR-Pesticide database were occupational in nature and nearly half of the incidents were of moderate (20 incidents) or high (4 incidents) severity. The remaining 28 incidents reported in SENSOR-Pesticides were of minor severity. The Agency will continue to monitor the epidemiology data, and -- if a concern is triggered -- additional analysis will be conducted.

¹¹ https://www.epa.gov/national-air-toxics-assessment/2014-nata-technical-support-document

¹² https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results#about

The information from the air monitoring data submitted by the PPA, air monitoring data available from CA ARB, the NATA assessment, and review of the incident and epidemiology data indicate that the non-occupational population is not likely to be exposed to ambient levels of phosphine greater than the regulatory or recommended exposure level values. The required ambient air monitoring data (SS-1076) is still required as it will provide information on actual ambient air concentrations corresponding to commodity fumigations in a high-use area.

3.0 Considerations of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf). As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Further considerations are also currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

4.0 Human Studies

Any data collected and used or relied upon in risk assessments are subject to ethics review pursuant to 40 CFR 26. While the phosphine worker monitoring data (MRID 45898301) meets the definition of "research involving intentional exposure of a human subject," the Agency's rule (40 CFR part 26 subpart Q) defines standards for EPA to apply in deciding whether to rely on research involving intentional exposure of human subjects. Based on the review of the Agency's rule and the ethics review of the two phosphine worker monitoring data submissions (MRIDs 45898301 & 50095601), no barrier in law or regulation to EPA reliance on these data in actions taken under FIFRA or §408 of FFDCA was identified (M. Arling, 9/17/2020, Memos).

5.0 Conclusions

EPA has not selected points of departure for risk assessment but is relying on various regulatory exposure levels for inhalation exposure to phosphine which exist to protect occupational workers [see Appendix A (Table A1.)]. All phosphine/metal phosphide end-use products are restricted use pesticides due to inhalation toxicity and are only for sale to and for use by Certified Applicators or trained personnel working under the direct supervision of a Certified Applicator. Air monitoring in real-time during fumigations is required and respiratory protection is required when concentrations exceed threshold levels identified on registered labels or are unknown. Qualitative dietary, occupational, and residential exposure; and aggregate assessments from the registered uses of phosphine and the metal phosphides (phosphine/metal phosphides) were all conducted and are detailed in the *Proposed Interim Decision (PID) for Phosphine and the Metal Phosphides*.

PERFUM was used in the phosphine assessment to model air concentrations from emissions around fumigation facilities that could be compared to regulatory or recommended exposure limit values. It is clear that given the number of possible permutations of PERFUM inputs and ways of presenting the outputs that there are many possible approaches for interpreting the results. Preliminary review of the modeled scenarios indicate a majority of phosphine concentrations are below the OSHA PEL regulatory limit of 400 ug/m³ with concentrations increasing with increased structure sizes and shorter stack heights.

Submitted air monitoring data from the PPA, included over 6,200 valid data rows that represent 575 fumigation treatments conducted at multiple locations in Canada, the United States, and Chile. Fumigations in six broad categories (bin, chamber, container, ship, structure, and tarp) and all three active ingredients (aluminum phosphide, magnesium phosphide, and phosphine gas) are represented in the database. An overwhelming number of samples that address potential exposures to unprotected workers or non-occupational bystanders (4286 out of 4332), were below the OSHA PEL. Monitoring data provided by CARB as well as review of the NATA data for phosphine result in air samples (collected during all periods of a fumigation process) and modeled ambient annual average air concentrations below the regulatory and recommended OSHA PEL, NIOSH REL and ST, and ACGIH TLV and Ceiling exposure limits.

6.0 References

- M. King, et. al., D410399, 9/11/2013, Phosphide (Al, Mg) and Phosphine. Human Health Assessment Scoping Document Supporting Registration Review.
- J. Johnston, MRID 50095601, 10/28/2016, Phosphine Concentrations Measured in Air at Fumigation Sites.
- T. Morton, D457813, 6/16/2020, Phosphine: Justification for the Qualitative Dietary Exposure Assessment.
- M. Arling, 9/17/2020, Memo, Ethics Review of "Phosphine Monitoring Data Collected from Various Types of Fumigation Sites."
- M. Arling, 9/17/2020, Memo, Ethics Review of "Phosphine Concentrations Measured in Air at Fumigation Sites."

Appendix A. Phosphine Regulatory or Recommended Limits

A.1. Occupational Exposure Limits							
Exposure Limit	Limit Values						
OSHA Permissible Exposure Limit (PEL) - General Industry See https://www.osha.gov/dsg/annotated-pels/tablez-1 <a href="https://www.osha.gov/dsg/annotated-pels/tablez-1 <a href=" https:="" td="" ww<=""><td>0.3 ppm (0.4 mg/m³) 8-hour TWA</td>	0.3 ppm (0.4 mg/m³) 8-hour TWA						
California OSHA Permissible Exposure Limit (PEL) See https://www.osha.gov/dsg/annotated-pels/tablez-1 https://www.osha.gov/dsg/annot	0.3 ppm, 8-hour TWA 1 ppm (1.39 mg/m³) (ST)						
National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) See https://www.osha.gov/dsg/anmotated-pels/tablez-1.html#niosh_rel and Appendix A - NIOSH Potential Occupational Carcinogens	0.3 ppm, 8-hour TWA 1 ppm (ST)						
American Conference of Governmental Industrial Hygienists - TLV See https://www.osha.gov/dsg/annotated-pels/tablez-1 html#niosh rel ACGIH ® 2019 Edition	0.05 ppm (0.071 mg/m³), 8- hour TWA 0.15 ppm (0.21 mg/m³) (C)						

TWA = time weighted average TLV = threshold limit value ST = Short-term exposure limit

C = Ceiling exposure limit