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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Occupational and Residential Exposure Assessment for the Use of Piperonyl Butoxide in Residential Outdoor Automatic Mister Systems

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The attached document addresses occupational and non-occupational (residential) exposures and risks for the use of piperonyl butoxide (PBO) in residential outdoor automatic mister systems.

The assessment was reviewed by HED's Science Advisory Council for Exposure (ExpoSAC) to ensure compliance with current HED policy as well as ExpoSAC standard operating procedures (SOPs) for conducting occupational and residential exposure (ORE) assessments.

1.0 Background and Purpose

PBO is a synergist used in a wide variety of pesticide formulations. Synergists are chemicals that lack pesticidal effects of their own but enhance the pesticidal properties of other chemicals. PBO is an ingredient in pesticide formulations used in both residential and commercial applications. Commercial uses include pesticides for agricultural food and nonfood crops, food and non-food processing commercial establishments (indoor and outdoor premises), agricultural structures, equipment, and premises both with and without animals present, and direct application to veterinary and farm animals. Residential uses include pest control in homes and outdoor domestic structures, on gardens, lawns, and ornamentals, and direct application to household pets. As a synergist, PBO's mode of action is to impede an insect's ability to breakdown pesticides like pyrethrum and the synthetic pyrethroids by inhibiting the mixed function oxidase system of the insect. PBO is available primarily in liquid formulations but is also available in powder, dust, and granular formulations. It is applied by commercial and residential applicators by a wide spectrum of application equipment methods. Comprehensive information on use patterns and formulations is provided in the Piperonyl Butoxide Master Label (PBO Task Force II, 2003).

This document specifically addresses exposures and risks associated with the use of PBO in residential outdoor automatic mister systems. Such systems, designed to control flying insects through foliar deposition, are widely used in commercial structures such as dairy barns, however are also registered for use in residential sites including home yards. These systems utilize an array of spray nozzles, fed from a central holding tank or reservoir, to automatically deliver a fine mist of dilute solution at specified intervals throughout the day.

2.0 Automatic Mister Systems Use Patterns

Specific reference to "automatic mister systems" is not made in the Piperonyl Butoxide Master Label however there is reference to use of PBO in outdoor domestic sites as a general, crack-and-crevice, or spot surface spray. Four PBO-containing products (EPA Reg. No. 1021-1785, 21165-24,1021-1800, and 655-797) identified in a Consumer Specialty Products Association (CSPA) discussion paper (CSPA, 2005), reference specific nozzle spray systems used in outdoor residential sites. The following is additional general use information from the CSPA discussion paper:

- Holding tanks or reservoirs are typically plastic with 30, 55, or 250 gallon capacity;
- Nozzle height is approximately 8 – 10 feet (i.e., off the ground);
- Nozzle spacing is approximately 10 – 15 feet apart along fences or foliage (i.e., perimeter separation);
- Automatic dispersions are set for 2 to 4 times per day for 30 to 60 seconds per event;
- Systems can be activated manually by homeowners.

Table 1 below shows the application regime used to assess exposures and risks associated with outdoor automatic systems.

Table 1: Outdoor Automatic Misters – Application Regimes							
EPA Reg. No.	% PBO soln	Amt soln sprayed (fl. oz./nozzle-min)	Nozzle coverage ¹ (nozzles/ft ²)	Application Rate ²			
				lb PBO/gal soln	lb PBO/ft ² -minute	lb PBO/ft ³ -minute	
						10' nozzle hgt.	8' nozzle hgt.
1021-1785	0.46	1.25	0.01/ft ²	0.0384	0.00000375	0.000000375	0.000000469

¹ Nozzle coverage for 1021-1785 is directly from label.

² Application Rate Calculations:

EPA Reg. No. 1021-1785

0.0384 lb PBO/gal soln = 8.345 lb prod/gal prod * 0.46% PBO soln

0.00000375 lb PBO/ft² - minute = 1.25 fl oz/nozzle-minute * 1 gal/128 fl oz * 0.0384 lb PBO/gal soln * 0.01 nozzle/ft²

Note: lb ai/ft³-minute rate was calculated by dividing the lb ai/ft² rate by the designated nozzle height (8 or 10 feet).

3.0 Hazard Identification

Table 2: Acute Toxicity of Piperonyl Butoxide				
Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
81-1	Acute Oral	41969001	LD ₅₀ = 4570 mg/kg (m) LD ₅₀ = 7220 mg/kg (f)	Category IV
81-2	Acute Dermal	41969002	LD ₅₀ = >2000mg/kg	Category IV
81-3	Acute Inhalation	41990001	LC ₅₀ = >5.9 mg/L	Category IV
81-4	Primary Eye Irritation	41969004	Minimally irritating	Category III
81-5	Primary Skin Irritation	41969003	Minimally irritating	Category III
81-6	Dermal Sensitization	41969005	Negative	Category IV

Table 3: Selected Endpoints for Assessing Occupational and Residential Risks for Piperonyl Butoxide			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary General Population	NOAEL= 630 mg/kg/day UF = 100 Acute RfD = 6.3 mg/kg/day	FQPA SF = 1X aPAD = <u>acute RfD</u> FQPA SF = 6.3 mg/kg/day	Developmental toxicity study, rats (Tanaka et al., 1995a) LOAEL = 1065 mg/kg/day based on decrease in maternal body weight gain
Acute Dietary Females 13-49 years	N/A	N/A	Acute Dietary Endpoint for General Population is considered protective for this population. No separate endpoint is selected.
Chronic Dietary (All populations)	NOAEL= 15.5 mg/kg/day UF = 100 Chronic RfD = 0.16 mg/kg/day	FQPA SF = 1X cPAD = <u>chronic RfD</u> FQPA SF = 0.16 mg/kg/day	Chronic oral toxicity study, dogs LOAEL = 52.8 mg/kg/day based on decrease in body weight gain, and increases in alkaline phosphatase activity, liver weight and hepatocellular hypertrophy

Table 3: Selected Endpoints for Assessing Occupational and Residential Risks for Piperonyl Butoxide			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term (1-30 days) and Intermediate-Term (1-6 months) Incidental Oral	NOAEL= 89 mg/kg/day	Residential MOE = 100 Occupational MOE= 100	Two generation reproduction study, rats LOAEL = 469 mg/kg/day based on the decrease in body weight gain of F ₁ and F ₂ pups at postnatal day 21
Short-Term Dermal (1 to 30 days); Intermediate-Term Dermal (1 to 6 months); Long-Term Dermal (>6 months)	N/A Dermal Absorption = 2%	N/A	No systemic, developmental and neurotoxicity concerns at the Limit Dose. Oral NOAELs with the dermal absorption factor result in dermal equivalent doses approximately equal to or higher than the Limit Dose. Therefore, no quantification is required. Piperonyl butoxide is classified as mild irritant. Contact should be avoided.
Acute Inhalation (≤ 2 hrs) (inhalation absorption rate = 100 %)	NOAEL= 630 mg/kg/day	Residential MOE = 100	Developmental toxicity study, rats (Tanaka et al., 1995a) LOAEL = 1065 mg/kg/day based on decrease in maternal body weight gain
Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months) Inhalation	Respiratory LOAEL= 3.91 mg/kg/day (0.015 mg/L)	Residential MOE = 300 Occupational MOE = 300	Subchronic inhalation toxicity study, rats Respiratory LOAEL = 3.91 mg/kg/day (0.015 mg/L) based on laryngeal hyperplasia and metaplasia
Long-Term Inhalation (>6 months)		Residential MOE = 1000 Occupational MOE = 1000	
Cancer	NA	NA	Classified as “Group C carcinogen” with RfD approach for quantification

4.0 Occupational and Residential Exposure and Risk Assessment

4.1 Exposure Scenarios

HED anticipates the following activities to result in potential exposure and risks to PBO via installation and use of automatic mister systems.

Occupational

- Inhalation exposure during mixing and loading liquid formulations for the systems’ holding tanks;

Residential

- Inhalation exposure during mixing and loading liquid formulations for the systems’ holding tanks;
- Bystander inhalation exposure during outdoor mister applications;
- Non-dietary incidental oral exposure on turf following outdoor mister applications;

Although potential for dermal exposure exists, a toxicological endpoint was not identified; therefore a quantitative dermal risk assessment will not be performed.

4.2 Occupational Exposure and Risk Estimates

Occupational exposure durations are expected to be acute (< 2 hours), short-term (1-30 days), and intermediate-term (1- 6 months). Long-term (> 6 months) exposures are not expected for this particular use. Assumptions, exposure factors, and calculation methodology are consistent with HED policy and standard operating procedures (SOPs) from the Science Advisory Council for Exposure (ExpoSAC).

Occupational Handler Inhalation Exposure

Table 4 below presents risk estimates for inhalation exposure during mixing/loading liquid formulations for the systems’ holding tanks.

Exposure Factors and Assumptions

The following assumptions and factors were used in estimating risks to occupational handlers from exposure to PBO:

- Average adult body weight is 70 kg;
- Baseline inhalation represents no respiratory protection;
- Inhalation unit exposures used for this scenario is from “Open Mixing/Loading Liquids” scenario from Pesticide Handler Exposure Database Surrogate Guide (PHED Version 1.1);
- Application rate (lb ai/gal soln) used is from a product label assumed to represent typical automatic mister systems (see Table 1);
- Holding tank size (55 gallons and 250 gallons) is based on information provided to SRRD from the registrants;
- Handlers (i.e., system maintenance workers) are assumed to fill 5 holding tanks per day.

Table 4: Occupational Handler Baseline Inhalation Exposure					
Application Rate (lb PBO/gal soln)	Reservoir size (gallons)	System Maintenance (tanks filled/day)	Daily Dose ¹ (mg/kg/day)	MOE ²	
				Acute (Target MOE = 100)	ST/IT (Target MOE = 300)
0.0384	55	5	0.0002534	3500000	22000
	250	5	0.0011516	770000	4800

¹ Daily Dose (mg/kg/day) = [Application Rate (lb PBO/gal soln) * Unit Exposure (1.2 ug/lb PBO handled) * Holding Tank Size (gallons/tank) * System Maint. (tanks/day) * Inhalation Abs. Factor (100%)] / [CF (1000 ug/mg) * Body Weight (70 kg)]

² MOE = Acute NOAEL (630 mg/kg/day) / Daily Dose (mg/kg/day) or ST/IT LOAEL (3.91 mg/kg/day) / Daily Dose (mg/kg/day)

4.3 Residential Exposure and Risk Estimates

Residential exposure durations are expected to be acute and short-term. Assumptions, exposure factors, and calculation methodology are consistent with HED policy and standard operating procedures (SOPs) from the Science Advisory Council for Exposure (ExpoSAC) and the SOPs for Residential Exposure Assessments.

Residential Handler Inhalation Exposure

Table 5 below presents risk estimates for inhalation exposure during mixing/loading liquid formulations for the systems' reservoirs.

Exposure Factors and Assumptions

The following assumptions and factors were used in estimating inhalation risks to residential handlers from exposure to PBO:

- Average adult body weight is 70 kg;
- Baseline inhalation represents no respiratory protection;
- Inhalation unit exposures used for this scenario is from “Open Mixing/Loading Liquids” scenario from PHED Version 1.1;
- Application rates (lb ai/gal soln) used is from a product label assumed to represent typical automatic mister systems (see Table 1);
- Holding tank size (55 gallons and 250 gallons) is based on information provided to SRRD from the registrants. It is assumed that a homeowner can prepare the dilute solution and re-fill the holding tank;
- Holding tanks filled per day (1).

Application Rate (lb PBO/gal soln)	Reservoir size (gallons)	System Maintenance (tanks filled/day)	Daily Dose (mg/kg/day)	MOE	
				Acute (Target MOE = 100)	ST/IT (Target MOE = 300)
0.0384	55	1	0.0000362	1700000	110000
	250	1	0.0001645	380000	24000

¹ Daily Dose (mg/kg/day) = [Application Rate (lb PBO/gal soln) * Unit Exposure (1.2 ug/lb PBO handled) * Holding Tank Size (gallons/tank) * System Maint. (tanks/day) * Inhalation Abs. Factor (100%)] / [CF (1000 ug/mg) * Body Weight (70 kg)]

² MOE = Acute NOAEL (630 mg/kg/day) / Daily Dose (mg/kg/day) or ST/IT LOAEL (3.91 mg/kg/day) / Daily Dose (mg/kg/day)

Residential Outdoor Bystander Inhalation Exposure

Table 6 below presents risk estimates for bystander inhalation exposure following an outdoor residential automatic mister application.

Exposure Factors and Assumptions for Acute Exposure

The following assumptions and factors were used in estimating acute inhalation risks to outdoor residential bystanders from exposure to PBO:

- Average body weights are 70 kg (adult) and 15 kg (toddler);

- Application rate (lb ai/ft³-min) used is from a product label assumed to represent typical automatic mister systems (see Table 1);
- The emission is to be treated as an “instant release” scenario. All active ingredient is assumed to be “thrown up” in the air immediately and available for exposure (100% active ingredient available) for the entire exposure duration;
- Inhalation rates are assumed to be 1.0 m³/hour (adult, light activities) and 0.7 m³/hour (toddler, light to moderate activities);
- Nozzle height outdoors is assumed to be 8 feet from the ground;
- Exposure duration is assumed to be 1 minute per day (0.0167 hours/day) – the entire duration of a nozzle spray.
- Exposure is assumed to encompass 1, 1-minute spray event that occurs in the morning or evening (i.e., exposure is to air concentration following 1, 1-minute spray event). *Note: this is assumed to be a conservative estimate for acute exposure duration (i.e., labels indicate spray durations may be less – 20-, or 30-seconds).*

Table 6: Residential Outdoor Bystander – Acute Inhalation Exposure and Risk Estimates					
Population Sub-Group	Application Rate (lb PBO/ft ³ -min)	Air Concentration ¹ (mg PBO/m ³)	Inhalation Rate (m ³ /hour)	Daily Dose ² (mg/kg/day)	Acute MOE ³ (Target MOE = 100)
Adult	0.000000469	7.50974	1	0.00179	350000
Toddler	0.000000469	7.50974	0.7	0.00585	110000

¹ Air Concentration (mg PBO/m³) = Application Rate (lb PBO/ft³-min) * CF (454000 mg/lb) * CF (35 ft³/m³) * # Spray Events (1) * Spray Duration (1 minute)

² Daily Dose (mg/kg/day) = [Air Concentration (mg PBO/m³) * Inhalation Rate (m³/hr) * Inhalation Abs. Factor (100%) * Exposure Duration (0.0167 hrs/day)] / Body Weight (kg)

³ MOE = Acute NOAEL (630 mg/kg/day) / Daily Dose (mg/kg/day)

Exposure Factors and Assumptions for Short-Term Exposure

The following assumptions and factors were used in estimating short-term inhalation risks to outdoor residential bystanders from exposure to PBO:

- Average body weights are 70 kg (adult) and 15 kg (toddler);
- Application rate (lb ai/ft³-min) used is from a product label assumed to represent typical automatic mister systems (see Table 1);
- The emission is to be treated as an “instant release” scenario. All active ingredient is assumed to be “thrown up” in the air immediately. Further, the chemical is assumed to be diluted in outdoor air at a ratio of 1 to 100 (i.e., 1%), and the pesticide is assumed to remain in the air at this concentration for the entire duration of exposure;
- Inhalation rates are assumed to be 1.0 m³/hour (adult, light activities) and 0.7 m³/hour (toddler, light to moderate activities);
- Nozzle height outdoors is assumed to be 8 feet from the ground;
- Exposure duration is assumed to be 5 hours per day for adults and 3 hours per day for toddlers.
- Exposure is assumed to encompass 2, 1-minute, or 2, 30-second spray events that occur in the morning or evening and are also assumed to occur within the 5-hour or 3-hour exposure duration interval (i.e., exposure is to total air concentration following 2, 1-minute, or 2, 30-second spray events).

Table 6: Residential Outdoor Bystander – Short-Term Inhalation Exposure and Risk Estimates						
Population Sub-Group	Application Rate (lb PBO/ft ³ -min)	Inhalation Rate (m ³ /hour)	Spray Duration (minutes)	Air Concentration ¹ (mg PBO/m ³)	Daily Dose ² (mg/kg/day)	ST MOE ³ (Target MOE = 300)
Adult	0.000000469	1	1	0.150195	0.010728	360
			0.5	0.0750974	0.005364	730
Toddler	0.000000469	0.7	1	0.150195	0.0210273	190
			0.5	0.0750974	0.0105136	370

¹ Air Concentration (mg PBO/m³) = [Application Rate (lb PBO/ft³-min) * CF (454000 mg/lb) * CF (35 ft³/m³) * # Spray Events (2) * Spray Duration (min)]/Dilution Factor (100)

² Daily Dose (mg/kg/day) = [Air Concentration (mg PBO/m³) * Exposure Duration (hrs/day) * Inhalation Rate (m³/hr) * Inhalation Abs. Factor (100%)]/ Body Weight (kg)

³ MOE = ST/IT NOAEL (3.91 mg/kg/day) / Daily Dose (mg/kg/day)

Residential Outdoor Non-Dietary Incidental Oral Exposure (Hand-to-Mouth, Object-to-Mouth, and Soil Ingestion)

Table 7 below presents risk estimates for outdoor incidental oral exposure to toddlers following an outdoor residential automatic mister application.

Exposure Factors and Assumptions

The following assumptions and factors were used in estimating risks to outdoor incidental oral exposure to PBO:

- Average body weight for a toddler 15 kg;
- The available turf transferable residue (TTR) is assumed to be:
 - 5% of the *total* potential deposition for one entire day (i.e., after all applications have been made for that day) for hand-to-mouth (HTM) activities;
 - 20% of the *total* potential deposition for one entire day (i.e., after all applications have been made for that day) for object-to-mouth (OTM) activities;
 - 100% of the *total* potential deposition for soil ingestion (SI) activities, and is located within the soil's uppermost 1 cm.
- Surface area is assumed to be:
 - 20 cm² for HTM activities (surface area of one to three fingers);
 - 25 cm² for OTM activities (represents the approximate area from which a toddler may grasp a handful of grass or “mouth” and object such as a toy);
- It is assumed that no dissipation occurs throughout the day;
- For soil ingestion a rate of 100 mg/day is assumed;
- Volume to weight soil conversion factor is 0.67 cm³ per gram of soil;
- The rate of hand-to-mouth activity is 20 events/hour for short-term exposure and 9.5 times/hour for intermediate-term exposure;
- A saliva extraction factor of 50% is assumed for HTM activities – representing the incomplete removal of residues on the hands using human saliva;
- Postapplication is assessed on day zero for all incidental oral scenarios (i.e., the toddler could be exposed to turfgrass immediately after one entire day of automatic mister application);
- Exposure duration is assumed to be 2 hours per day for HTM activities.

- The following calculation inputs used for these scenarios can be found in Table 1:
 - Application Rate (lb PBO/gal soln);
 - Nozzle Coverage (nozzles/ft²);
 - Nozzle Emission Rate (fl oz/nozzle-minute)

Table 7: Non-Dietary Outdoor Incidental Oral Exposure and Risk Estimates								
EPA Reg. No.	Application Rate ¹ (lb PBO/A-min)	Spray Cycles		Potential Total Daily Deposition ² (lb PBO/A)	Exposure Scenario	Potential Daily Dose ³ (mg/kg/day)	MOE ⁴ (Target MOE = 100)	
		Duration (min)	#/Day					
1021-1785	0.1634	1	2	0.3267	HTM	0.0048	18000	14000
					OTM	0.001221183	73000	
					SI	0.0000163638	5400000	

¹ Application Rate (lb PBO/A-min) = [Application Rate (lb PBO/gal soln) * CF (43560 ft²/A) * Nozzle coverage (Nozzles/ft²) * Nozzle Emission Rate (fl oz/nozzle-min)] / CF (128 fl oz/gal)

² Potential Total Daily Deposition (lb PBO/A) = Application Rate (lb PBO/A-min) * Spray Cycle Duration (min) * Spray Cycles (#/day)

³ HTM Daily Dose (mg/kg/day) = [Pot Daily Deposition (lb PBO/A) * Default TTR (5%) * CF (4.54E8 ug/lb) * CF (2.47E-8 A/cm²) * Surface Area of Hands (cm²/event) * Event Frequency (events/hour) * Saliva Extraction (50%) * CF (0.001 ug/mg) * Exposure Duration (2 hrs/day)] / Body Weight (kg). Only short-term HTM exposures are shown.

OTM Daily Dose (mg/kg/day) = [Pot Daily Deposition (lb PBO/A) * Default TTR (20%) * CF (4.54E8 ug/lb) * CF (2.47E-8 A/cm²) * CF (0.001 ug/mg) * Surface Area Ingestion (cm²/day)] / Body Weight (kg)

SI Daily Dose (mg/kg/day) = [Pot Daily Deposition (lb PBO/A) * Default Soil Residue (100%/cm) * CF (4.54E8 ug/lb) * CF (2.47E-8 A/cm²) * CF (0.67 cm³/g soil) * CF (1E-6 g/ug) * Soil Ingestion Rate (mg/day)] / Body Weight (kg)

⁴ MOE = ST/IT NOAEL (89 mg/kg/day) / Daily Dose (mg/kg/day)

5.0 Risk Summary

Short-term residential bystander inhalation risk for toddlers is the only scenario of concern. Bystander inhalation risk for toddlers is of concern when exposure is to the PBO air concentration resulting from 2, 1-minute spray durations (MOE_{Toddlers} = 190). When exposure is to 2, 30-second spray durations, risk is not of concern (MOE_{Toddlers} = 370).

6.0 Risk Characterization and Recommendations for the Risk Assessment

The exposure durations used in the short-term inhalation exposure (5 hours/day for adults, 3 hours/day for toddlers) represent the 95th percentile values for time spent outdoors at a restaurant/picnic area (USEPA, 1997). During this exposure period, the individual is assumed to be exposed to the average air concentration following 2 spray events, each lasting a period of either 1 minute or 30 seconds. Inhalation risks of concern are seen when exposure results from air concentrations after 2, 1-minute spray durations. Although this spray duration is considered reasonable, lower spray durations (i.e., 20- or 30-second durations) may be more representative of actual system rates. Standard label language for use rates could provide a more refined risk assessment. Label language requiring systems to activate at times when people are not present (i.e., EPA Reg. No. 1021-1785) or systems with motion detectors would also significantly reduce inhalation exposure.

Risks were calculated based on automatic dispersions (i.e., 2-6 pre-set spray events per day) throughout the day. It was noted in the CSPA discussion paper that the systems can be manually activated by the homeowner. Although costs of re-filling and service maintenance costs would likely deter homeowners from frequent or over-use, label language indicating appropriate daily spray cycles should be considered.

7.0 References

Consumer Specialty Products Association, c/o Pyrethrin Steering Committee/Joint Venture and Piperonyl Butoxide Task Force II. Discussion Paper: Intermittent Aerosols, Residential Mosquito Mistlers, and Dairy Barn Mistlers. July 22, 2005.

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