UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

SUBJECT: Antimicrobials Division's Recommendations For the Bronopol HVAC Use. PC Code 216400.

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Executive Summary

This memo provides a summary of the Antimicrobials Division's (AD) risk assessment for Bronopol's HVAC use and recommendations. In brief, handler risks were assessed for air duct applications (ULV fogger, low pressure handwand, and an airless sprayer) and as an application to evaporation A/C sumps. Both dermal and inhalation margin of exposures (MOEs) are not of concern for the short-, intermediate-, and long-term durations based on oral NOAELs (assuming 100 percent dermal absorption) of 10 and 40 mg/kg/day chronic and developmental studies, respectively. Short- and intermediate-term total MOEs range from 1800 to 32,000 while long-term total MOEs range from 460 to 7,900. Although the exposure to the active ingredient is assessed using single layer of clothing, no gloves, and no respirator, additional PPE is warranted based on the acute toxicity (e.g., Toxicity Category I eye). Although exposure data for air duct spraying is not available, the surrogate assessment is deemed to represent a high end estimate for externally treated air ducts. For those instances where workers need to crawl inside the air ducts, additional PPE is required as specified in this document.

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Although no monitoring data are available to estimate the potential postapplication exposures to individuals residing or working in treated buildings, a high end screening-level assessment is provided. The postapplication inhalation assessment is based on a bounding assumption of a saturation concentration in the occupied building for greater than 6 months. MOEs for the long-term inhalation exposure range from 85 for children to 550 for adults. The assumption of reaching a saturation concentration is overly conservative. However, assuming no ventilation and maintaining that saturation concentration for greater than 6 months and still achieving the MOEs as presented in Table 2 indicates that postapplication risks are not of concern. No attempt was made to estimate the exposure to aerosols that may be generated while using ULV foggers and/or airless sprayers. Instead, administrative controls are recommended for the label.

Background

Bronopol is a microbiocide/microbiostat that controls bacterial and algal growth in industrial, commercial, and residential air conditioning and humidifying systems. Bronopol (EPA Reg. No. 67212-1 BBJ Microbiocide) is composed of 95 percent of the active ingredient 2-Bromo-2-nitropropane-1,3-diol and can be applied at maximum rates of 100 ppm (1.68 lb per 1,000 gallons) in sumps and 200 ppm in air ducts. Bronopol is packaged as a two-part product. The product contains the crystalline formulation of bronopol and an accompanying container of solvent. The two containers are mixed and then diluted with water. Although not a restricted use pesticide (RUP), it is not intended for residential sale. The proposed label suggests treatment at intervals of 6 months to every two years and not more than monthly.

Sump applications consist of mixing the two-part product and open pouring into the evaporation sump. Air duct application equipment includes ULV foggers, low pressure handwands, or airless sprayers. Other application techniques on the label also include mopping and wiping the duct work. For this assessment, the typical use that would result in the higher exposures are the foggers/handwands/airless sprayers. Applications can be made by workers either outside or inside the air ducts. At this time the Antimicrobial Division does not have any data to estimate the dermal and inhalation exposures to those individuals that crawl inside air ducts. The proposed label indicates the following for applications from within the HVAC system:

> *"Caution - Technicians working inside air ducts should be fully trained and certified in confined space operations and procedures. OSHA has full guidance for such operations."*

Finally, the label recommends that the *"...fans and blowers in the section of duct being treated should be turned off during application... or isolated until treatment is complete. There is no need to have occupants leave the building during applications."*

Results

The estimated handler risks for external applications into air ducts and sump treatments, as presented in the Versar assessment, are summarized in Table 1. These risks represent workers wearing long pants, long sleeved shirts, no gloves, and no respirators. The MOEs for all scenarios are above 100 and are not of concern. The ULV fogger exposure is expected to be less than that of the airless sprayer. However, applications from within the HVAC system are not assessed.

Table 1. Bronopol Dermal, Inhalation, and Total Exposure/Risk Assessment for Applicators.

Location	Use	Scenario[a]	Use[c] Rate	Gallons Used[d]	Short- and Intermediate MOEs[e]			Long-term MOEs[f]		
					Dermal	Inhalation	Total	Dermal	Inhalation	Total
Residential Homes	Air Ducts	ULV Fogger	200 ppm	No Data						
		LP handwand		1.75	34000	430000	32000	8500	110000	7900
		Airless sprayer			11000	490000	11000	2700	120000	2600
Commercial Buildings	Evaporation A/C Sump	Mixing/loading	100 ppm	1000	2600	120000	2600	660	30000	650
	Air Ducts	ULV Fogger	200 ppm	No Data						
		LP handwand		10	6000	76000	5500	1500	19000	1400
		Airless sprayer		10	1900	86000	1800	470	22000	460

[a] Scenarios based on equipment types listed on the label and are typical of air duct applications.
b Dermal and inhalation unit exposures (UE) are based on PHED data for application using an airless sprayer (house stain application), mixer/load/applicator for a low pressure handwand, and open mixing/loading for the evaporation A/C sump use. Clothing scenarios for all unit exposures are based on long pants, long sleeved shirts, and no gloves. Final decision on PPE should consider toxicity categories fo r the end use product.
[c] Maximum concentrations of 100 ppm for the sump and 200 ppm for air ducts are based on EPA Reg. 67212-1.
[d] Amount of gallons used per day per individual is based on highend estimates for cleaning air ducts and sump volumes.
[e] Short- and intermediate-term MOE= NOAEL/Daily Dose. Where oral NOAEL is 40 mg/kg/day (Target MOE 100) and assuming 100 % dermal absorption.
[f] Long-term MOE = NOAEL/Daily Dose. Where oral NOAEL is 10 mg/kg/day (Target MOE 100) and assuming 100 % dermal absorption..

The postapplication concern for Bronopol treatments is the potential for inhalation exposures. Dermal exposure is expected to be minimal because the sprays are made within the duct work. Because no monitoring data are available for Bronopol treatments, a high end inhalation assessment using a saturation concentration (no ventilation) of 0.136 mg/m^3 is presented in Table 2.

Table 2. Inhalation Assessment for Postapplication Exposures Resulting from Air Duct Applications.

Setting	Population	Air Conc. (mg/m^3)	Inhalation[a] Rate (m^3/day)	Short- and Intermediate-term Inhalation MOEs[b]	Long-term Inhalation MOEs[b]
Residence	Adult	0.136	11.3[a]	1600	390
	Child		8.7[a]	340	85*
Commercial	Adult	0.136	8[b]	2,200	550
School building	Adult	0.136	8[b]	2,200	550
	Child		3.2[a]	920	230

[a] Inhalation rate are from EPA Exposure Factors Handbook, average rate of 11.3 m^3/day for adult females and average rate for children (age 1-12 yrs) of 8.7 m^3/day. For schools, child inhalation rate was based on 8 hour exposure and an inhalation rate of 0.4 m^3/hr for sedentary activities (EPA, 1997).

[b] MOE= NOAEL/Inhalation Daily Dose. The oral NOAEL for adults is 40 mg/kg/day for short- and intermediate-term exposure and the oral NOAEL is 10 mg/kg/day for long-term exposure.

* See Conclusion for a description of uncertainties and limitations of this MOE.

Conclusion

The handler risks for external applications are not of concern for any exposure duration. Exposure to the ULV fogger is believed to be less than that for the airless sprayer. However, no data are available to assess exposures to applications within the HVAC systems (i.e., confined space). EPA has concerns regarding the adequacy of the label language for confined spaces as Bronopol is not a RUP. EPA has discussed with the registrant the fact that a full description of OSHA's rule on the label would not be practical and suggests additional label language in the *Recommendation Section* below. Finally, technical (98.5 percent) Bronopol is a Tox Category I for acute dermal and eye toxicity and is a dermal irritant. Note: End use product is 95 percent. These concerns can be controlled with the addition of PPE.

The postapplication risks for dermal exposure is expected to be minimal. The inhalation risks are estimated using Bronopol's saturation concentration because of the lack of monitoring data. The short- and intermediate-term inhalation MOEs range from 340 to 2200 with most at or above 1000. The long-term MOEs range from 85 to 550. Both the short/intermediate-term and long-term assessments are overly conservative in that they assume saturation concentration and no ventilation. Because of these assumptions in this particular case, the MOE of 85 should not be of concern. To refine these risks would require either monitoring data or estimates of the air concentrations using a range of building ventilation rates. Potential inhalation exposures to aerosols escaping the from vents in the ducts during application was not assessed.

Recommendations

The handler and postapplication risk concerns can be mitigated using the following suggested label modifications:

- All Bronopol handlers should wear a minimum of protective eye wear, long pants, long sleeved shirts, and chemical resistant gloves based on the acute toxicity categories (Tox I eye and dermal and classified as a dermal irritant).

- If applications are to be made by workers in the duct work, then OSHA confined space regulations should be followed. The preferred method of compliance is by ventilating the duct work with an airflow of approximately 50 CFM per SF of duct cross section. If this is not feasible, then OSHA confined space regulations should be followed. These requirements include testing the atmosphere and use of adequate respirator protection. If the level of contaminants cannot be determined, then maximum respiratory protection (SCBA or airline with an escape bottle) should be used. In addition, workers applying Bronopol within the air ducts are required to wear chemical resistant coveralls, chemical resistant gloves, and chemical resistant goggles. The full face respirator should also be equipped with a spray mist pre-filter in addition to the charcoal filters.

- For applications that may create aerosols the air ducts are required to be under negative pressure with an outdoor exhaust. This requirement is believed to be prudent because the label allows the occupants to be present during application and we have no data to indicate that aerosols will not escape from the duct work into the rooms.. Other mitigation measures such as purging the air ducts with outdoor air prior to occupancy may be appropriate and should be discussed with the registrant. But, the purge with outdoor air is not necessary if ventilation has been provided during application

- Bob Baker of BBJ emailed a memo to Dennis Edward on 11/27/2002 (see Appendix A) regarding the wording for label languages. The final wording should be consistent with the above recommendations.

APPENDIX A

Bob Baker of BBJ emailed a memo to Dennis Edward on 11/27/2002 as following:

1. Currently overall precautionary statements read, "Wear goggles or face shield and rubber gloves when handling." We will revise that to read, "Wear goggles or face shield, long pants, long sleeved shirts and rubber gloves when handling."

2. Add the following to Section 3.3.2 (Application from Within the HVAC System) of the label, "Applicators working inside of the duct system must wear chemical resistant coveralls, chemical resistant gloves, and chemical resistant goggles or a full face respirator equipped with activated charcoal filters. In addition the duct work should be ventilated with an airflow of approximately 50 CFM per square foot of duct cross section. If this is not possible, OSHA confined space regulations should be followed and the requirements for a permit required space apply. These requirements include testing the atmosphere and use of adequate respirator protection. If the level of contamination can not be determined, then maximum respiratory protection (SCBA or airline with an escape bottle) should be used."

3. Add the following to Section 3.3.1 (Application from Exterior of the HVAC System), "During ULV, mist or spray application, the duct system interior must be maintained under slight negative pressure (0.15-0.25 In. WG) with an outdoor exhaust. Avoid higher pressure differentials that would be likely to disrupt the coverage pattern."

There is no sound reason for purging the air ducts with outdoor air prior to occupancy. The label states that the smallest particle size should be 15 microns. Particles of this size deposit very quickly. The air flow that is mandated in the above requirements will provide sufficient purge to assure that any smaller particles inadvertently generated will be exhausted to the outdoors. Providing an additional purge would be both unproductive and burdensome to the applicator.

We discussed application to porous surfaces and you suggested delaying inclusion of that use. I am concerned about that because at tie present time applicators routinely use currently registered products that are clearly labeled for "hard surfaces" on fiberglass lined ducts without any corresponding directions to guide them. By including the fiberglass substrate use and providing clear directions, we best protect against misapplication. Further, there is no reason to believe this is an inappropriate application or represents a greater risk. We discussed several areas where the agency might have concerns:

1. Such applications may utilize more product mass and thus represent a greater risk. - The data we supplied in the exposure study was developed assuming that all duct interiors were porous fiberglass lined and thus

represented a clear worst case. The Hazard indexes developed during that study (adult = 0.00102 and child = 0.0026) are well below 1. The risk level is quite low.

2. There has been concern expressed about leaving fiberglass surfaces wet and thus promoting future growth. - That concern falls from the nature of the product currently most widely used. It is a chlorine dioxide based product that uses water as a carrier. Although chlorine dioxide is capable of rapidly destroying all organisms it is exposed to, it has an extremely short half life (30 minutes or so) after which it no longer has any Antimicrobial properties. If the fiberglass surface becomes re-contaminated with spores prior to the time the fiberglass is completely dry, the residual moisture will support re-growth. That is currently happening because the existing product is routinely applied to fiberglass surfaces leading to the concerns that were communicated to you. You will recall that, in our formulation, the water is not just a carrier but is a solvent that helps bond the active to the surface matrix and fixes it to that surface. The Antimicrobial protection extends for a considerable time (months) following application. Thus, any residual moisture available when new spores land on the protected surfaces will actually facilitate the fungistatic efficacy of the active. Under its current registration, BBJ MICROBIOCIDE is used in air conditioning equipment that is often lined with fiberglass. Users routinely report to us that the fiberglass lining is subject to over spray of moisture off of the cooling coil and often becomes highly contaminated with fungal growth. They consistently report success in controlling that growth as well as growth on cooling coils, in drain pans and on other components by using our product. That is the reason we believe so strongly that this is an important application.

3. Fungal growth may have penetrated so deeply into the fiberglass matrix that treatment will fail. - I agree that is a valid concern. It is for that reason that we have directed at the beginning of the label that the duct must be brought to the cleanliness level mandated in NADCA Standards before treatment. In addition, the directions in 3.4.3 specifically mandate that the fiberglass lining or duct board must be replaced if effective control is not established following two applications. The needless replacement of fiberglass lining or duct board systems is an expensive undertaking. If a simple, low cost treatment can preclude that expense, it is a valuable contribution to the industry and the public.

4. Antimicrobial coatings currently available have proven to be an effective solution for the industry. - Such coatings an order of magnitude more expensive than the treatment we advocate. More important, the agency has completed an RED for the active in the coating that is currently used in the industry and has declined to re-register air duct uses of that active. That would seem to indicate, at a minimum, that the manufacturer of that product will need to develop and submit the same type of data and label directions plus the agency will need to perform the same comprehensive review that we have participated in. At the end of that process, the agency may not be able continue the registration of that product. Finally, I do not believe the presence of a product in the marketplace is a valid reason to withhold

entry to potential competitors.

There may be questions relative to treatment of porous materials that need to be answered. We will not obtain those answers, however, by delaying the time when we begin to seek them. Growth of organisms on the surfaces of fiberglass in air duct is a widely recognized and documented problem that has serious economic and comfort impacts for the public and businesses. I believe we offer an inexpensive and low risk alternative for addressing that wide spread problem. Rather than delaying the porous materials portion of this application let us consider positive alternatives.