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

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EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MEMORANDUM

SUBJECT: **Review of "Toxicity Study, Indoor Air Quality Evaluation of Disinfection Solution" and "Toxicity Study, Indoor Air Quality Exposure Effects Assessment a Toxicology Review of VOC Emissions"**

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DP Barcode (s): D280107

Pesticide Chemical No.: 064001

Review Time: 50 Hours

MRID #: 455569-01, 455667-01

I. BACKGROUND

The Risk Assessment and Science Support Branch (RASSB) has been asked to review two studies submitted by the Sporicidin International. The following table provides information related to these studies.

Title:	1. Toxicity Study, Indoor Air Quality Evaluation of Disinfection Solution, and 2. Toxicity Study, Indoor Air Quality Exposure Effects Assessment a Toxicology Review of VOC Emissions
Product:	Sporicidin® Brand Disinfectant Solution & Permacide Disinfectant & Sanitizer
Sponsor:	Sporicidin International 121 Congressional Lane Rockville, MD 20852
Performing/Analytical Laboratories:	Air Quality Sciences, Inc. 1337 Capital Circle Marietta, GA 30067
Study Director & Author:	Air Quality Sciences, Inc.
Report Date:	November 14, 2001

II. EXECUTIVE SUMMARY

An indoor air quality evaluation and a toxicology review of VOC emissions were performed by Air Quality Sciences, Inc., for Sporicidin® Brand Disinfectant Solution (EPA Reg. No. 8383-3). Sporicidin® is used as a cleaner, disinfectant, and deodorant in hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

For the test, Sporicidin® was sprayed onto a clean metal plate until beads of liquid appeared on the surface. The plate, which had been weighed previous to the spraying, was weighed again and then placed into a heated chamber where chemical emissions were measured. As reported in AQS Report #07729-01, the air supply to the chamber was maintained at a temperature of 38°C ± 2°C and relative humidity at 50% ± 5%. Also, the air exchange rate during the test was 1 air change/hour (ACH). Emissions were monitored over a 96-hour period for formaldehyde, total volatile organic compounds (TVOC), and

individual volatile organic compounds. Formaldehyde and other target aldehydes were not detected. According to the report, the primary VOCs that were emitted included phenol, hydroxypropoxypropanol, and dipropylene glycol. Levels of detected volatile organic compounds decreased over time. Additionally, fragrances and heavy alkylated benzenes were emitted, while formaldehyde and other target aldehydes were not.

Using the measured concentrations from the environmental chamber test, emission factors were calculated and used to predict air concentrations in an indoor setting. According to the Indoor Air Quality Evaluation Study Report, the USEPA's Indoor Air Exposure Model was utilized to model the air concentrations with the following assumptions: "air within open office areas of the building is well-mixed at the breathing level zone of the occupied space; environmental conditions are maintained at 50% relative humidity and 23°C (73°F); there are no additional sources of these pollutants; and there are no sinks or potential re-emitting sources within the space for these pollutants. The space was assumed to be 32 m^3, with an air exchange rate of 0.8 air changes per hour (ACH) and 1 m^2/m^3 of treated metal surface."

In the second report, "Indoor Air Quality Exposure Effects Assessment, a Toxicology Review of VOC Emissions", VOCs measured in the indoor air quality study for Sporicidin® were reviewed in terms of possible adverse health effects and adverse sensory perception effects, as indicated by irritation and odor. Predicted levels of VOCs were assessed for: (1) regulatory compliance (California Proposition 65); (2) permissible occupational exposure limits; (3) government guidelines for cancer and non-cancer risk; and (4) sensory perception effects (irritation and order). The evaluation assumes that human exposure would not occur until 8 hours after application of the Sporicidin®. The report concludes that occupational exposure levels would not be exceeded, cancer risks would be below USEPA's established limit $1x10^{-6}$, non-carcinogenic health effects would not be expected, and no sensory irritation would be expected. The report indicates that total volatile organic chemical levels may cause discomfort and headaches and odors due to phenol and decanal emissions would be expected.

Generally, the submitted reports need more detailed data and discussions. The environmental chamber study was conducted at a temperature of 38°C (100°F) and 1 ACH, while the modeling, performed using the USEPA's Indoor Air Exposure Model, assumed exposure conditions occurring at 23°C (73°F) and 0.8 ACH. Emission factors developed from data collected at the much higher temperature should not be used as input into the model where the assumed temperature is lower. The use of a different temperature and air change rate for the modeling than those used during testing should be explained, and, given these differences, the validity of the modeling results should be justified. Also, the reports do no clearly state how many samples were run for the test. It appears that only one sample was tested which would be an insufficient number.

It should be noted that the cover sheets of both reports indicate that these studies were performed for "Sporicidin Brand Disinfectant Solution and Permacide Disinfectant and Sanitizer (EPA File Symbol 8383-RN and Reg. No. 8383-3)." The reports themselves never refer to the Permacide Disinfectant and Sanitizer, so it is not clear if it is the same formulation as the Sporicidin® or if Permacide should be included under the "Product Name". If these reports are indeed meant to be applicable to both these products, then an explanation should be provided on how the two products are related and if the results are meant to represent application of the Permacide Disinfectant and Sanitizer, as well as the Sporicidin®.

III. DATA GAPS AND UNCERTAINTIES

A. Toxicity Study, Indoor Air Quality Evaluation of Disinfection Solution (455569-01) (AQS Report # 07729-01)

1. According to the Study Report (page 3, "Air Concentration Determinations"), the USEPA's Indoor Air Exposure Model was "specifically modified to accommodate this product and chemicals of interest." No details on these modification were provided in the report. A description of the model, a full explanation of changes to the model, a listing of all input parameters, and an example modeling run should be included in the report.

2. During the testing, the air supply to the chamber was maintained at a temperature of 38°C (100°F) and 1 ACH, while the modeling, performed using the USEPA's Indoor Air Exposure Model, assumed exposure conditions occurring at 23°C (73°F) and 0.8 ACH. It appears that volatiles would be emitted more quickly under the higher temperature and, along with the higher ACH or air change rate, would result in a higher emission factor that decreases more quickly than for the lower temperature and ACH. The use of a different temperature and air change rate for the modeling than those used during testing should be explained, and, given these differences, the validity of the modeling results should be justified.

3. According to Table 1 of the Study Report, "Environmental Chamber Study Parameters for Sporicidin International", three trial runs indicated an application rate of 27.6 g/m^2 ± 9.9 g/m^2. The three trial runs are not mentioned anywhere else in the report. Details of each measurement taken should be provided. Also, based on the fact that only one sample identification number is provided in this table, it appears that only one sample was run in the environmental chamber as part of this study (no other information is provided in the Study Report). If this is the case, it should be clearly stated in the report. Furthermore, based on the discussion of the required number of replicates in Section g(10) in OPPTS 875.1000, "Background

for Application Exposure Monitoring Test Guidelines," this is not a adequate number of replicates to assess exposure. Justification should be provided for only evaluating one sample or more samples should be evaluated and results revised.

4. The table note beneath Table 2 in the Study Report, "Summary of TVOC Emission Factors and Predicted Air Concentrations," indicates that the "initial 3- and 8-hour points exceeded the linear calibration range of the method; these results are from a subsequent test performed on this product with adjusted sample collection volumes, under same environmental parameters. Results are normalized for weight and product applied." A discussion of this problem and the mentioned subsequent test is not presented in the Report. Details on any problems and variations from the initial test protocol should be provided and discussed in the Report.

5. As shown in ASTM D 5116-97, the emissions factor is calculated based on the measured concentrations obtained from the environmental chamber testing. This Report only contains the calculated values for the emissions factors. The measured concentrations are not reported, nor is the formula used to calculate the emissions factors presented. The Report should present the raw data collected from the testing as well as a sample calculation indicating how the emissions factor was determined.

6. Predicted air concentration are not reported for the individual volatile organic compounds that are shown in Table 6.

7. Table 7 in the Study Report, "Summary Data for Disinfectant Solution", compares 8-hour measurements of the applied product to common indoor air quality criteria. OSHA limits for air contaminants (29 CFR 1910.1000, Table Z-1) should also be included in this table as two detected volatile organic compounds, formic acid and phenol, have permissible exposure levels (PELs) listed in this standard.

B. Toxicity Study, Indoor Air Quality Exposure Effects Assessment a Toxicology Review of VOC Emissions (455667-01) (AQS Report #07729-02).

1. Table 1, "Calculated Emission Rates and Predicted Concentrations of Compounds Identified from Sporicidin Brand Disinfectant Solution," does not include all the compounds that had emissions measured at 8 hours after product application as shown in Table 6, "Emission Factors of Identified Individual Volatile Organic Compounds", of AQS Report # 07729-02.

2. Equation 1 in Appendix A, Page 1, indicates the formula used to calculate the average daily concentration of a given compound in the workspace, C_{avg}. The emission rates shown in Table 1 of this Report are in units of $\mu g/m^2/hr$ (Note that

in AQS Report # 07729-02 these are identified as emission rate factors) while in Equation 1 the units for emission rate are µg/hr. Based on discussions presented in AQS Report # 07729-02, this average daily concentration, C_{avg}, is computed by the USEPA's Indoor Air Exposure Model and not by a simple formula. Clarification needs to be presented on how C_{avg} is calculated and the source of and units for the parameters in the formula. Citations for all the formulas shown in this Appendix should be provided.

3. A citation for Equation 2 in Appendix A, Page 2, needs to be provided. As shown in the Report, using the parameters indicated does not result in an average daily lifetime exposure concentration, C_{LT}, in units of µg/m^3, instead the resultant units are (µg-d)/(m^3-y).

4. A citation for Equation 4 in Appendix A, Page 2, needs to be provided. As shown in the Report, using the parameters indicated does not result in an average daily lifetime exposure concentration, C_{LT}, in units of µg/m^3, instead the resultant units are (µg-hr)/(m^3-y).

5. As shown in Appendix A, Page 3, Equation 5, used for calculating the hazard index, is not correct. The inhalation rate (10 m^3/day for a worker) is missing from the numerator and body weight (70 kg for an adult) is missing from the denominator (see USEPA's "Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)" (December 1989) for details on calculating intake from inhalation of airborne chemicals. The calculated intake (in units of mg/kg-d) is divided by the Reference Concentration (RfC) (mg/kg-d)$^{-1}$ to obtain the hazard index.

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