



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

JAN 19 2000

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Non-Dietary Exposure Considerations for **MICROBAN ADDITIVE "B"**
Bacteriostatic/Fungistatic Agent Containing the Active Ingredient
5-Chloro-2-(2,4-dichlorophenoxy) phenol.

TO: Connie Welch, Chief
Robert Brennis, Product Manager, Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist *Doreen Aviado 1/18/2000*
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: Timothy McMahon, Ph.D. *[Signature] 1/18/2000*
Senior Toxicologist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief *[Signature] 01.19.2000*
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Registrant: Microban Products Company

DP Barcode: D256201 (S562387)

**Pesticide
Chemical No.:** 054901

**A.I. Chemical
Name:** 5-Chloro-2-(2,4-dichlorophenoxy) phenol
(Tradenames: *Triclosan*, and *Irgasan DP-300*)

EPA Reg. No.: 42182-1

Action Requested: A non-dietary human exposure assessment in support of a proposed "new use" for MICROBAN ADDITIVE "B" in fabricating certain ice making equipment component end products.

Summary of Findings: Based on the nature of the human exposures associated with the proposed "new use", RASSB anticipates limited non-dietary exposure potential via the dermal and/or inhalation routes for handlers involved in application and post-application activities. In addition to the low exposure profile, the acute toxicity profile did not trigger the need for a non-dietary occupational exposure/risk assessment. Therefore RASSB determined that at this time it is not necessary to conduct a formal non-dietary exposure/risk assessment to support the additional use sites. In support of this label amendment RASSB has previously conducted separate reviews for assessing dietary exposure¹ and dietary risk² associated with ingestion of ice containing residues of MICROBAN ADDITIVE "B". To supplement these dietary assessments, an overview of the non-dietary human exposure considerations are presented in this review.

BACKGROUND:

The Antimicrobials Division (AD), Regulatory Management Branch II, received a label amendment submission for MICROBAN ADDITIVE "B", a manufacturing use product (MUP) registered since August 15, 1983 as a materials preservative of commodity end products. MICROBAN ADDITIVE "B" contains 99% of the active ingredient 5-Chloro-2-(2,4-dichlorophenoxy) phenol, also known as *Triclosan*, and *Irgasan DP-300*, and is currently approved for use as an additive incorporated into various plastic polymers and related media such that the finished end products contain 0.10% to 0.50% by weight of the active ingredient.

MICROBAN ADDITIVE "B" is a bacteriostatic and fungistatic additive, supplied as a resinous concentrate (polymeric pellets), to enable industrial end users of this MUP to fabricate end products which are finished treated articles. MICROBAN ADDITIVE "B" is approved for incorporation into apparel, construction and building materials, films, floor coverings, home furnishings, housewares, industrial products, personal care products, sporting goods, and other miscellaneous goods as specified on the product labeling. The technical source product for the 99% active ingredient is

The registrant seeks to amend the current registration to reflect the addition of certain industrial ice making equipment components to the list of approved end products specified on the product labeling (i.e., water pans, piping, tubing, and guards).

¹ Refer to separate dietary exposure review memorandum by Robert Quick, Residue Chemist, for this submission under D257880.

² Refer to separate dietary risk review memorandum by Timothy McMahon, Sr. Toxicologist, for this submission under D257879.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

HUMAN EXPOSURE CONSIDERATIONS:

The Risk Assessment and Science Support Branch (RASSB) was asked to assess any potential non-dietary exposures to handlers associated with the proposed "new use" in ice making equipment. It should be noted that the non-dietary exposure considerations covered under this review supplement the dietary exposure assessment and dietary risk assessment reviews conducted by AD/RASSB in support of this label amendment submission. Based on a review of the submitted labeling, administrative materials, and documents on file in the regulatory jacket for MICROBAN ADDITIVE "B", RASSB determined that conducting a formal non-dietary exposure/risk assessment was not necessary at this time based on the following considerations:

- 1) RASSB conducts human exposure/risk assessments when based on the antimicrobial pesticide's toxicity, certain toxicological criteria are triggered (e.g., the Acute Toxicity Studies indicate Category I or II Toxicity) and the human activities associated with the use patterns can lead to potential adverse exposures to occupational/residential handlers and bystanders. For this proposed label amendment, neither the toxicity nor the exposure criteria are triggered.

The MICROBAN ADDITIVE "B" product has been classified under Toxicity Category III based on data accepted by the Agency for the [REDACTED] source product and acceptance of acute toxicity data waiver arguments presented by the registrant in an April 2, 1999 submission. The product labeling reflects the "CAUTION" signal word and precautionary statements for Toxicity Category III. The registrant asserts that by nature of the product formulation type (i.e., resinous polymeric pellets) the toxicity of the MUP is significantly reduced since the dilution of the 99% raw active ingredient (a.i.) into a polymeric based system decreases the amount and availability of the active ingredient for human exposure to 10% a.i. in the MUP. Also, the solid physical state of the pellets negates any inhalation exposure concerns. The a.i. is not a dermal sensitizer, and use of personal protective equipment (PPE) and proper handling as stipulated on the labeling is anticipated to minimize dermal and eye contact.

The potential non-dietary exposures associated with this proposed label amendment use are characterized as "occupational" not "residential" exposures. Occupational handlers involved in the mixing/loading/application of MICROBAN ADDITIVE "B" 99% a.i. concentrate during fabrication of certain ice making equipment components are anticipated to conduct these tasks using PPE and primarily by automated, closed systems of delivery, and automated engineering controls/manufacturing processes for industrial fabrication by injection molding, compression molding, extrusion and dip-coating. Industrial postapplication handling of the finished component end products (i.e., the finished treated articles containing 0.10% to 0.50% by weight of the a.i.) is anticipated to pose negligible exposure concerns for occupational handlers at the "parts" manufacturing plant, during ice machine assembly, and during subsequent maintenance/servicing tasks requiring dermal contact with the component parts. (It should be noted that the fabricated parts are housed inside the ice making machinery and are not intended to be handled by industrial workers/users during normal operation of the ice machine.)

- 2) This proposed "new use" actually represents a label amendment for additional "use sites", not a new "use pattern". Both the type of media (i.e., polyethylene, polystyrene, and vinyl plastisol)

into which the MICROBAN ADDITIVE "B" is to be added and the levels of incorporation into the proposed ice making equipment component end products, are consistent with currently approved ranges of incorporation for end products made of similar media (i.e., ranging from 0.1% to 0.5% by weight of the final product).

- 3) At time of initial MICROBAN ADDITIVE "B" product registration AD/RASSB did not conduct a formal human exposure assessment or human health risk assessment for the dietary/non-dietary use patterns associated with this chemical. Since *Triclosan* is slated for reregistration in FY 2001, thorough assessments for human exposure/risk will be conducted for each of the registered MICROBAN ADDITIVE "B" use patterns as part of the RED chapter development process.
- 4) Of primary concern to RASSB in reviewing this amendment action were the potential dietary exposures associated with the proposed ice making equipment use (i.e., ingestion of ice containing chemical residues of the a.i.). The dietary risk assessment concluded that: "Using conservative assumptions, it is clear that, as a percentage of the Reference Dose, the risk from ingestion of Triclosan resulting from this use is below the Agency's level of concern." Since RASSB anticipated that human exposure to the a.i. via the oral route would represent greater potential for adverse effects than via the dermal/inhalation routes, the results of the dietary assessment further support the preliminary assertion that limited potential exists for adverse non-dietary exposures to occupational handlers involved in the fabrication, assembly and servicing of MICROBAN-treated ice making equipment components.

CONCLUSIONS:

Based on this preliminary assessment, RASSB anticipates limited potential for adverse non-dietary exposures associated with this proposed "new use" via the dermal or inhalation route for occupational handlers involved in the mixing/loading/application of MICROBAN ADDITIVE "B" concentrate in the fabrication of certain ice making equipment components and from industrial post-application handling of the finished component end products.

Note to the PM Team:

Please note the following comments regarding the submitted draft labeling:

- Registrant should revise the "Applications" statement under the "Directions For Use" to read: "...finished product contains 0.10% to 0.50% by weight of the active ingredient." to be consistent with the administrative materials documents provided with this submission.
- In the "Precautionary Statements" section, the registrant must specify the actual personal protective equipment which must be worn rather than stating "Wear appropriate personal protective equipment."

cc: Doreen Aviado/RASSB/AD (7510C)
Chemical File
Circulation