Letters to the Editor

Is Triclosan Susceptible to Contamination?

To the Editor:

Ciba-Geigy Corporation directs attention to the report that appeared in the September 1984 issue of *Infection Control* by Barry et al. The article, "Serratia Marcescens Contamination of Antiseptic Soap Containing Triclosan: Implications for Nosocomial Infection," reports certain findings and conclusions concerning one of our products, triclosan, marketed under the trade name Irgasan DP 300, a broad-spectrum antimicrobial agent primarily used in topically applied products.[1]

The Barry report concludes that data generated using an in vitro challenge protocol indicates that OR/Scrub®, a liquid handwash containing 1.0% triclosan, is susceptible to bacterial (primarily gram-negative species) contamination and lacks efficacy and safety for its use in the operating rooms, intensive care units, and other high-risk environments of hospitals. Additionally, information was quoted from the FDA's OTC Topical Antimicrobial Products Tentative Final Monograph (1978) to support the contention that triclosan is unsafe as a single antimicrobial active ingredient in surgical scrubs, health care personnel handwashes, and patient pre-operative preparations.

We agree that the Barry report developed data that indicate that there was a potential preservation problem with the original OR/Scrub® formulation. The report, however, strongly implies that triclosan is the reason for the documented contamination and could contribute to the proliferation of the contaminating organism. This conclusion is not supported by the evidence.

The authors themselves discuss other handwash products that contain other antimicrobial agents (chlorhexidine, iodophors, and hexachlorophene), in most cases used at higher concentrations than triclosan, documented to have been susceptible to bacterial contamination. The report also attempts to correlate the lack of gram-negative antimicrobial activity of hexachlorophene to triclosan based on chemical structure similarity. In fact, the two compounds are chemically different and in vitro testing documents significant difference in the antimicrobial activity between hexachlorophene and triclosan.[2]

As far as the preservation problem is concerned, the manufacturer of OR/Scrub® has reformulated the product to include a very effective preservative system that withstands the challenge of all the bacterial species mentioned in the Barry report and confirmed in the report's addendum[3] (Oleson P, Friend M, unpublished data, 1984).

One should distinguish between antimicrobial agents used to prevent product deterioration ("preservatives") and antimicrobial agents included for topical activity. The fact that a handwashing product has been found to be contaminated should not reflect adversely on the efficacy of an agent included as a skin antimicrobial. Triclosan itself is not susceptible to contamination. While handwash products containing antimicrobials such as triclosan, chlorhexidine, povidone-iodine or hexachlorophene may, depending on the particular product composition, be self-preserving, it should not be assumed by a supplier or user, that a skin antimicrobial ingredient will automatically also protect a product against microbial contamination. The finished product in its original container should be evaluated by the supplier for preservation capacity using an appropriate challenge test, for example USP or CTFA methods. Ciba-Geigy supports the promotion of triclosan as a topical antimicrobial agent with extensive data derived from in vivo test protocols such as glove juice tests, basin tests, and artificial contamination of hands with bacteria (including gram-negative species) to more closely simulate actual in-use conditions[4] (Cox AR, unpublished data, 1981), (Schenkel A, Opferkuch M, Furia T, unpublished data, 1966).

Based on their data, Barry et al conclude that handwash products containing triclosan as a single active ingredient should be considered unsafe and ineffective for use in operating rooms, intensive care wards, and areas where high-risk patients reside. To reinforce their conclusion, the FDA Antimicrobial Tentative Final Monograph (1978) is referenced. The reference, however, refers to an unsubstantiated hypothesis published in the original Tentative Final Monograph (1978) that postulates that prolonged use of triclosan-containing wash preparations on the skin could result in the overgrowth of gram-negative bacterial species. This theory has never been proven, either by scientific investigation or through practical experience and has been a continuing unresolved issue between the FDA and Ciba-Geigy. Ciba-Geigy disputes this theory based on data derived from controlled studies and in-use experience. Our investigations demonstrate

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that while triclosan is effective at reducing the bacterial level on skin, it does not eliminate all resident bacterial microflora on the skin, thus one-way pressure for the proliferation of a competing organism does not exist. Furthermore, many experts agree that normal dry skin is not a hospitable environment for the survival of gram-negative species. Long-term studies measuring the consequences of exposure to triclosan, through frequent use of handwash products, failed to generate evidence that gram-negative bacteria would colonize and proliferate on the skin of the test subjects.[5-7]

In May 1982, Ciba-Geigy received notification from the Division of OTC Drug Evaluation, Office of Drugs recommending that the status for use of triclosan in surgical scrubs, personnel health care handwashes, and patient pre-operative preparations be changed from a not approved (Category II) to a conditional approval (Category III) (W. Gilberston, personal communication, 1982). Since receiving this notification, Ciba-Geigy has generated (and submitted to the FDA) additional data to support our position that triclosan is safe and efficacious for use in the clinical environment[4,8] (Cox AR, unpublished data, 1981).

The antimicrobial effectiveness of a topically applied product is a function of the total formulation rather than a single ingredient. Based on the facts we have presented, it is clear that the conclusions of Barry et al are unsubstantiated.

REFERENCES

1. Irgasan DP 300 product bulletin, CIBA-GEIGY (1983). MIC table pp 4, 5.
2. Regos J, Zak O, Solf R, et al: Antimicrobial spectrum of triclosan, a borad-spectrum antimicrobial agent for topical application. *Dermatologica* 1979; 158:72-79.
3. Barry MA, Craven DE, Goularte TA, et al: Serratia marcescens contamination of antiseptic soap containing triclosan: Implications for nosocomial infection; Addendum. *Infect Control* 1984; 5(9):427-430.
4. Bartzokas CA, Corkill JE, Makin T, et al: Assessment of the remanent antibacterial effect of a 2% triclosan-detergent preparation on the skin. *J Hyg Camb* 1983; 91:521-528.
5. French MLV, Eitzen HE: The Influence of O-R Scrub on Gram-Negative Bacterial Infections and Environmental Over-Growth in a Newborn Intensive Care Unit. Vol. XIV, Master File #916, 1974.
6. Hool G, Ziegler WJ: Handwash Pilot Study with Liquid Soap Formulations Containing 1% Irgasan DP300. Vol XIV. Master File #916, Ref. 8, 1974.
7. Williams JB, Brown J Jr, Jungerman E: An evaluation of the effect of antibacterial soaps on the microbial flora of the hands, *Developments in Industrial Microbiology*, 1976; 17:185-191.
8. Bartzokas CA, Gibson MF, Graham R, et al: A comparison of triclosan and chlorhexidine preparations with 60% isopropyl alcohol for hygienic hand disinfection. *J Hosp Infect* 1983; 4(3):245-255.

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The authors of the article in question respond to Findley and Spainhour's concerns.

Dr. Findley and Mr. Spainhour appear concerned that our findings with OR Scrub® (Huntington Laboratories), a product containing 1% triclosan, may have implications for their product Irgasan DP-300 (Ciba-Geigy). We agree with their conclusion that topical antiseptic agents should be evaluated as a function of their total formulation rather than on the basis of the active ingredient. For that reason, we carried out our investigations with OR Scrub®, rather than triclosan alone. Our data emphasized three points: 1) "In-use" OR Scrub® was contaminated with *Serratia marcescens*, 2) In vitro studies clearly indicated that OR Scrub® had limited activity against *S. marcescens* and *Pseudomonas aeruginosa*, 3) OR Scrub® was not only more expensive but less effective against *S. marcescens* than a non-antiseptic soap (Wash®), also produced by Huntington Laboratories. OR Scrub was reformulated after our manuscript was in press, and we added the addendum to demonstrate that the "new" OR Scrub® was improved. However, we remain concerned over its low activity against *S. marcescens*, a common nosocomial pathogen. Our manuscript contained no data on other products containing triclosan.

The importance of testing the final formulation rather than the active antimicrobial ingredient is emphasized in our manuscript. Because 1% triclosan was the only ingredient in OR Scrub® claimed to be antimicrobial, we assumed that the product's lack of activity was due to the triclosan rather than the "inert" ingredients added as preservatives. We did not provide data or draw any specific conclusions regarding the efficacy of Irgasan DP-300, and we invite Dr. Findley and Mr. Spainhour to provide specific data on the efficacy of their product against *S. marcescens* and *P. aeruginosa*. We, and other readers of *Infection Control*, do not have ready access to unpublished reports, master files, or FDA docket numbers to which they refer. However, of the two medical literature references cited,[6,8] triclosan was used in concentrations greater than 1%, or was combined with another agent that had antimicrobial activity. Unfortunately, neither of these reports used *S. marcescens* as a test organism.

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IV Administration and Tracheostomy Care in the Home

To the Editor:

Please notify me if you have information concerning intravenous administration and tracheostomy care in the home. Our home health agency feels the frequency of changing IV tubing in the hospital might not be necessary in the home. Reimbursement sources are stressing resterilization and aseptic technique in the home for trach care.

We have not been able to locate durable supplies to withstand resterilization.

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Sue Crow, RN, MSN, Nurse Epidemiologist at Louisiana State University Medical Center offers the following reply.

There have been no studies relating infection control practice to home health care. National organizations have not addressed appropriate infection control guidelines for this area. With this in mind, we must make judg-