

November 1, 1988

H. W. Dietz

ACTIVITIES REPORT FOR OCTOBER, 1988

1. Geons

The National Sanitation Foundation (NSF) issued a draft report "Comparative Evaluation of Plastic Products under NSF Standards 14 and 61." The study was undertaken to compare the toxicology requirements and testing results under NSF Std. 14 "Plastic Piping Components and Related Materials" with those in NSF Std. 61 "Drinking Water System Components--Health Effects." Coverage under the two standards overlaps with respect to materials requirements for potable water contact. Samples of PVC and CPVC pipe and fittings were included. In general, it was found that products that were acceptable under Std. 14 would be acceptable under Std. 61. While there were some troublesome statements, one in particular was cause for concern. It was implied that mutagenicity data would be required on extracts of the products to comply with Std. 61. If this were true, it would entail considerable unnecessary expense for each product. Such was never the intent of the Health Effects Committee which established the toxicity requirements for Std. 61.

In order to set the record straight, I attended the Industry Forum and NSF Std. 14 Joint Committee meetings. In discussions with NSF staff and during the meetings, it was made clear that only in the event of a lack of identity or nonpredictable migrating species and/or lack of mutagenicity data for migrants would mutagenicity tests be required on total extractants. Furthermore, for those products containing essentially the same ingredients, information could be used for a class of products.

Dr. McClelland felt this was a major clarification. She had been under the impression that mutagenicity tests on product extracts were to somehow test the synergism of the migrants.

It was the consensus of the Industry Forum and the Std. 14 Joint Committee that Std. 14 be revised to include reference to Std. 61 for health effects evaluation with a minimum 2-year phase-in period for products currently listed under Std. 14.

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As a result of reviews of a couple of Geon compounds, which reversed the claimed FDA status of both, I have been receiving many more requests for review of Geon compounds. I have reviewed nine Geon compounds with requests to review an additional 14 compositions.

2. Estanes

Ortho Pharmaceuticals, Canada, is progressing on the use of Estane polyurethane polymers in the fabrication of condoms. Ortho holds a patent on the manufacture of condoms from polyurethanes which was not pursued for several years. Due to increased demand, they are pursuing this patent.

I participated in a meeting with representatives from the Estane Group, Ortho Pharmaceutical, and the University of Windsor in Toronto. We had an excellent comprehensive review of the project by all three parties. Dr. Ilse, Ortho, and I reviewed the toxicological concerns to be addressed to assure ourselves and regulatory agencies of the safety of the end product. Ortho will perform the toxicological evaluation and testing of the final polyurethane composition when established.

Mary Conrardy, Wisconsin Pharmacal, consulted with me regarding additional testing requested by FDA on their "female" condom. I also supplied her with published reports regarding long term implantation of polyurethanes and lack of extractable MDA from polyurethanes except at highly elevated temperatures.

3. No Foul

Ms. Cool, EPA special review manager for organotins, informed me verbally that we would be granted an exemption from the release testing requirements of the Organotin Antifouling Paint Control Act of 1988. She requested copies of the current NoFoul label, MSDS, product bulletins, and amount manufactured in 1988.

Copies of the latest product bulletins, particularly the Technical Background bulletin, are outdated and/or obsolete. They describe various application including pleasure craft, water intakes, pilings, etc. in addition to sonar domes.

These are being submitted with a strong caveat that they were outdated and that marketing attempts except for sonar dome use have been abandoned. Projected 1988 production, label and MSDS will also be submitted as requested.

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4. Hydrophilics

A Federal Register notice permitting the use of Carbopol 1342 as an inert ingredient in pesticide formulations has not been published as yet. However, Monsanto which wishes to use C-1342 in No-Mix and has been in contact with EPA, has ordered an initial 10 lbs. of C-1342 for evaluation trials.

The Cosmetic, Toiletry and Fragrance Association has finally issued an adopted name for Carbopol 1342. The official CTFA adopted name is "Acrylates/C10-30 Alkyl ACrylate Crosspolymer." This name can be used for cosmetic labeling. Carbomer 1342 N.F. could also be used for such labeling.

Since the NF has finally published the carbomer monographs, requests have been received for similar monographs in the British Pharmacopeia. A BP monograph for Carbomer 934, 934-P already exists, but is somewhat different than the USP-NF monograph. I have written to the British Pharmacopeial Commission requesting information regarding the establishment of monographs for those Carbomers recently published by USP-NF.

5. RJF International

Some problems related to acceptance of current RJF (formerly BFG) products have arisen with the sale of the Fabricated Polymers Division.

KoroKlear Vinyl Strip and Sheet has had USDA acceptance for hanging refrigerator doors. I have informed USDA of the sale of this product and requested that they supply an acceptance letter to C. Schmidt, RJF.

KoroKlear Vinyl Strip and Sheet has been under NSF Standard 51 "Food Service Equipment." I have informed NSF of the ownership change and instructed them to contact Ms. Schmidt for further listing.

Since the sale of the former Salem plant, I have completed numerous NSF submissions for Jeans' Extrusions for the Marietta products they have purchased. This last month I received requests from Jeans' Extrusions for submission of three Marietta vinyl compounds to NSF. To help ease the transition and since Marietta purchases the PVC resin from the Geon Division, I have continued this service. I have informed Ms. Schmidt that unless other arrangements are established, I will not be able to continue this service.

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I have sent copies of all such current NSF submissions to her and to Marietta to serve as examples.

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cc: R. K. Hinderer
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