

August 1, 1986

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Activities Report - July, 1986

I. Hydrophilics

The Cosmetic, Toiletry and Fragrance Association (CRFA) has officially adopted the generic name Carbomer 1342 for Carbopol 1342. Because Carbopol 1342 is an acrylic copolymer rather than a homopolymer, polyacrylic acid, there had been hesitancy on the part of CTFA to assign the same generic name (Carbomer) as has been assigned to the other Carbopols.

Abbott Labs is interested in using Carbopol 934P in an oral pediatric pharmaceutical. They had requested copies of all toxicity studies done on C-934P. Rather, we have set up a meeting with Abbott representatives to discuss the toxicity studies and other data. From the detailed list of questions submitted prior to the meeting, it is apparent that the present toxicity data on C-934P will not satisfy Abbott's needs.

To resolve several questions, I have discussed the regulatory requirements for toll manufacture of polycarboxylic acid, U.S.P. with the FDA. According to the FDA, the toll manufacturer must be registered as a drug establishment, be solely responsible for good manufacturing practice, and meet USP monograph requirements. Labeling requirements were also determined. BFG's warehouse need not be registered so long as it is only a warehouse.

II. National Sanitation Foundation (NSF)

I attended the NSF Drinking Water, Health Effects Task Group meeting July 8, 9. The mission of this group has been defined so as to develop an accurate, precise, expeditious procedure to evaluate the safety of direct and indirect water additives. Much discussion centered on confidentiality, use of data and "threshold of regulation" concepts. It was apparent that NSF has an ultraconservative approach. Much work needs to be done. It seems that this will be a long, laborious process. We have, as requested, written a proposed evaluation procedure to be submitted for review by the task group.

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The Fabricated Polymers Group wants to obtain NSF listing for Koroklear hanging door strips under NSF Std. 51. These hanging door strips are used for "walk in" freezers and refrigerators. We cancelled our Std. 51 listing for rigid Geon compounds at the beginning of the year. In order to list the hanging door strips in the quickest time possible, it was necessary to reinstate the listing for the Geon 87300 compounds and then add the door strips. We will later cancel the Geon listings.

III. Estanes

A competitor claims to have FDA acceptance for his polyurethane for use as bottle cap liners. I had received a letter from him citing his FDA clearance. The regulations he cited are the same ones the Estanes are cleared under. These do not permit polyurethanes to be used as bottle cap liners. I have written to FDA for an opinion on the use of such resins in the above use.

IV. FDA-PVC Proposal

FDA has taken no further action on their PVC food contact proposal. The comment period closed June 6, with no adverse comments filed by consumer or other groups.

V. No Foul

I have not been able to determine if Master Processing has registered with EPA as a pesticide producer.

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