August 1, 1986

H. W. Dietz

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 polycarbophil, 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.

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.

W. C. Bachtel

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September 2, 1986

H. W. Dietz

Activities Report for August, 1986

1. Hydrophilics

A Drug Master File (DMF# 6542) has been established with the FDA for Carbopol EX-83. This is BFG's brand name for calcium polycarbophil, U.S.P. Some potential customers have been awaiting the establishment of the DMF for referrals to their applications.

Marketing, R&D and I met with 22 representatives of Abbott Laboratories to discuss the toxicity tests performed on Carbopol 934-P and other technical aspects. Abbott Labs is interested in using Carbopol 934-P in an oral pediatric preparation to be distributed world-wide. They have indicated a substantial usage potential.

They were disappointed that the last toxicology tests had been done by Industrial Biotest. Abbott had conducted a literature search but were unaware of the original Bristol-Meyers published work. Concern was expressed over the residual benzene content and we were asked about a benzene-free Carbopol. Abbott is very anxious to obtain a sample of benzene-free Carbopol as soon as possible. All in all, the meeting went quite well.

Production has questioned the inclusion of the heavy metals and carboxylic acid analyses in the proposed carbomer monographs as published in the Pharmacopeial Forum. In addition, an error in the viscosity measurement for C-910 was pointed out. Also, it was questioned as to why no monograph was proposed for Carbomer 1342.

It was pointed out that these issues had been discussed previously by all and the resultant proposed monographs had been reviewed about two years ago without comment before being submitted to U.S.P.-N.F. No monograph has been proposed for Carbomer 1342 since no permanent product specifications have been agreed on and established. Permanent specs must be established before a monograph is proposed, they cannot be changed indiscriminately. These issues are to be resolved at the September Carbopol GMP meeting.

To help the marketing group track the pharmaceutical uses of the Carbopol resins, I have prepared a list of all referrals to the Carbopol Drug Masterfile. The list goes back to 1970 and includes the customer, customer contact referral date, Carbopol resin and NDA or IND number and application.

2. National Sanitation Foundation (NSF)

As requested at the water additives Health Effects Task Group meeting, I submitted a proposed decision tree and diagram for evaluation and acceptance of direct and indirect water additives. The BFG submission is on the agenda for discussion by the Health Effects Task Group at the September 23-24 meeting.

We have attempted to obtain NSF listing under Standard #51 for Koroseal Vinyl Strip and Sheet (Fabricated Polymers) to meet major competitors' claims. The proposed use is for hanging refrigerator and freezer doors. So far, this has been a real fiasco. First, NSF wrongly advised me on the procedural steps necessary. As advised, we would have to reinstate delisted Geon products first, then list the Koroklear strips, then cancel the Geon listings. The end result would have been greatly increased costs. I have resolved this matter. Secondly, although the USDA and FDA permit FD&C Red #2 for use in food contact applications, NSF refused our listing because of the use of Red #2 at a level of less than 0.006%. We are reformulating the product without the colorant.

NSF has recently begun a Total Organic Carbon (TOC) testing program for water and food additive standards. They are using this as a screening test. If the results are above 5 ppm TOC then they require analytical definition of the extracts and base acceptance on their known or inferred toxicity. So far this is to be used only for evaluating new ingredients. If used properly, this could be less rigorous than FDA requirements for indirect food additive requirements.

3. CPVC

DuPont wants to use CPVC in a food contact application involving various fruit juice concentrates. CPVC does not now have FDA clearance for food contact applications. DuPont has requested any migration/extraction data available to submit to the FDA. I have reviewed two extensive extraction sutdies on PVC and CPVC water pipe. Before we can release these studies, we must obtain permission from the Vinyl Institute. Steps are being taken to obtain the required releases.

4. Geon 351

Geon 351 is listed in the Registry of Toxic Effects of Chemical Substances (RTECS) as a positive animal carcinogen. Allied was prepared to use Geon 351 in a product until they noted the animal carcinogen notation. This notation is