May 5, 1987

H. W. Dietz

ACTIVITY REPORT FOR APRIL, 1987

1. Hydrophilics

A petition has been submitted to EPA requesting clearance for the use of Carbopol 1342 as an inert pesticide ingredient for use in nonfood and food crop applications. The immediate application is as a drift-flow control agent in Monsanto's herbicide, Roundup, for use in recreational and domestic lawn applications.

EPA has recently issued a new policy for inert pesticide ingredient clearance which includes a minimum data set requirement. The data set includes product chemistry, mammalian toxicology, genotoxicity, ectotoxicity and environmental fate. Testing costs could exceed $200,000. In accord with EPA's suggestion, we have requested an exemption from the data requirements. Our request is based on the similarity of Carbopol 1342 to the other Carbopol resins and their relative low order of toxicity in general.

The Cosmetic, Toiletry and Fragrance Association (CTFA) is reviewing the monographs for acrylic polymers used in cosmetics. They have requested updated product lists and additional information for their review. I am working closely with the product group to review and update the list of hydrophilics for which we wish to have CTFA monographs.

The UPS-NF Carbomer monographs have been on "hold" due to one standards committee member's objection to the inclusion of a benzene limit. IN a recent telephone conversation, Mr. Theimer, USP, indicated that the particular committee member would withdraw his objection if benzene were listed as an impurity on the Carbopol label. This he felt would insure that the pharmaceutical manufacturer was aware of the residual benzene.

I discussed Mr. Theimer's suggestion with the product group. They have no intention of listing benzene on the labels. In my response to Mr. Theimer, I noted that BFG must comply with the OSHA Hazard Communication Standard. Consequently, although benzene is not on the Carbopol label, an MSDS which lists residual benzene must be supplied to each customer. This will hopefully satisfy USP.

2. National Sanitation Foundation (NSF)

I attended the NSF Drinking Water Health Effects Task Group meeting April 23 and 24. Significant progress was made on the Health Effects product evaluation guidelines. The proposed guidelines are essentially the same as those proposed by BFG except that 90-day toxicity studies are required rather than 28-day studies at Level 2 exposure.

The guidelines will be redrafted, a background document prepared and then circulated to the task group, peer review group and NSF Joint Committee for review. It is anticipated that the final document can be completed with one more meeting in September.

3. Estanes

A May 20 meeting has been scheduled with the FDA, Dow, DuPont and BFG to develop an acceptable protocol to amend 21CFR177.2600 to include the polyether urethanes. Such clearance would permit polyether urethanes to be used in food conveyor belts, hoses, etc. Dow, DuPont and BFG have agreed to sponsor a joint petition and share the necessary work.

USDA acceptance was requested for the use of Estanes 54600 and 54610 greens 515 in conveyor belts for Habasit Company. Our original request was denied. Due to personnel changes, USDA could not find previous clearances granted for some of the Estane components. A call to USDA straightened out the problem and Habasit was given acceptance for their belts with the above Estane compounds.

4. Vinyl compounds

With more emphasis on gaining a greater share of the medical and food contact applications market, the vinyl division is concerned that Good Manufacturing Practice (GMP) for these products is being followed. I met with Fred Krause to discuss GMP as it pertains to compounded vinyl products. As a result, I visited Pedricktown to discuss GMP with plant personnel and examine the facilities. From what I observed, Pedricktown, with a few minor exceptions, is doing a very good job complying with GMP. At Fred Krause's request, I will visit the Louisville facility for a similar audit May 8.

Abex 33S has been used as an emulsifier in Geon 121X10. Geon 121X10 has been sold as an FDA acceptable resin. With the recent revelation that Abex 33S does not have clearance for food contact applications, the need for a

product recall or customer notification was discussed. I reviewed a customer-applications list. The products manufactured from Geon 121X10 are such that emulsifier exposure from their use would be vanishingly small and thus no public health hazard. Consequently there is no need for a customer notification or product recall.

5. Hycar Elastomers

President Fine Corp., Taiwan, is licensed to produce several Hycar elastomers for BFG. I reviewed recipes for nine Hycars produced in Taiwan for their FDA acceptance. All nine of these Taiwan produced Hycars have the same FDA clerances as their counterparts made in the U.S.A.

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