

November 3, 1986

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Activities Report for October, 1986

1. Polyurethanes

The second phase of extraction studies on the Estane polyetherpolyurethanes is near completion. The qualitative results obtained will provide a base for discussions with the FDA for clearance in repeated use articles.

It was learned that Dow is also doing work toward obtaining FDA acceptance for similar polyetherpolyurethanes. Dow utilizes the same polyether-chain extender and isocyanate as BFG. The resins differ in the ratios of the reactants and additive packages. DuPont has suggested that BFG and Dow join efforts to obtain FDA clearance. I have set up an exploratory meeting with Dow at DuPont for early December.

2. PVC

Amvrol, a division of Wrigley's, wants to use a flexible PVC compound as a package for a thumb shaped hard candy sucker. The sucker is to be hot molded in the PVC film at 275°F. Geon 86153, a DOP plasticized compound is being evaluated. I have expressed my concerns over the possible adulteration of the candy with the phthalate plasticizer and the tin stabilizer in this compound. I am working with the Geon group to find a solution.

The Geon group has learned that just because a product is represented as "FDA approved" it does not mean it can be used in all applications. An antifoam represented as "FDA approved" was to be used in a number of PVC resins for can coating applications. I found the clearance for this product to be very limited and not applicable to can coatings. As a result, this defoamer will be removed from the five PVC resins involved.

Alcoa uses three flexible Geon compounds for capliner applications. They require a current FDA certification letter in their files for each compound. At the request of the Geon group I prepared and sent appropriate certification letters to Alcoa for compounds PVC-A, 111-73-25-10, and 111-73-25-7.

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USP Biological Tests for Plastics were performed on Geons 84702, 84756, 86153 and 87455. These tests are performed as an indication of the suitability of a plastic formulation for various medical applications. Many potential customers require the results of these tests before consideration of a product. The tests on these compounds were performed under the most severe conditions, normally not used for PVC. Three of the samples passed; only Geon 87455 failed due to a reaction to the systemic injection in mice. This compound will be retested under the normal PVC conditions.

3. USDA

We received USDA acceptance for Good-rites K-XP120, KXP82D and K-XP83N as ingredients in boiler water treatment, steam lines or primary cooling loop formulations.

We are attempting to obtain USDA acceptance for Good-rite K-7058, 7058N and 7058 as rinse aids in cleaning compound formulations.

4. Hydrophilics

The Calvert City Carbopol plant is due for FDA inspection at any time. Also, the plant now fully recognizes that all the Carbopol 900 resin series are pharmaceutical products and must be produced using Good Manufacturing Practice (GMP). Therefore, because of some concerns of D. Henneke, I performed a GMP audit of the Carbopol facilities on October 8. The plant appears to be in good shape except for some housekeeping problems due to construction. There will also need to be more detailed recordkeeping (similar to that now used for C-934-P) for the other 900 series.

The group has now decided to proceed with the NF monographs for the 900 series since they must comply with GMP regardless of whether USP-NF monographs do or do not exist.

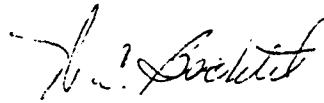
I have requested Cosmetic, Toiletry and Fragrance Association (CTFA) generic names for Carbopols 1706, 1724, 1731, 1754 and 940-A. The first four Carbopol resins are being used as a plasticizer or binder in toilet soap applications.

Carbopol 940-A is in actuality Carbopol 934-P produced by the new single pass technology for P&G. It will replace C-940 in Crest toothpaste until non-benzene Carbopol can be produced.

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Due to labeling provisions, P&G has asked that we attempt to have CTFA assign Carbomer 940-A as a generic name for this specially produced C-934-P.



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