

May 1, 1986

H. W. Dietz

ACTIVITIES REPORT - APRIL, 1986

1. PVC-FDA Proposal

BFG's comments on FDA's PVC proposal were submitted to the Agency April 1, 1986. Briefly, we supported SPI's comments and further, submitted USDA Prior Sanction letters for Polyblends (PVC-nitrile rubber blends) for use in conveyor belting for meat and poultry products. These uses were not covered by the FDA proposals.

SPI's comments which in general supported the Agency proposals were modified somewhat to reflect BFG's concern regarding the diffusion of vinyl chloride monomer (VCM).

The National Sanitation Foundation filed comments regarding the RVCM levels in water pipe. NSF presented data to justify a 2 ppm RVCM in water pipe, rather than the FDA-proposed 50 ppb.

A 60-day extension until June 5, 1986 for comments was granted at the request of a couple of companies due mainly to problems with the proposed analytical method.

Recent analytical results on some BFG flexible PVC compounds indicate the RVCM level is less than 2 ppb, well below the FDA-proposed limit of 5 ppb.

2. Hydrophilics

I reviewed the clearance of the Carbopol, Carboaset and Good-rite K-700 resins as inert ingredients in pesticide formulations. All of the Carbopol and K-700 resins, if neutralized to the sodium salt, and 18 Carboaset resins have clearance under 40 CFR 180.1001 as inert ingredients in pesticide formulations applied to growing crops or raw agricultural products. Product data sheets for each group of resins have been prepared based on this review.

We have requested the Cosmetic, Toiletry and Fragrance Association (CTFA) to adopt the generic name Carbomer 1342 for Carbopol 1342 for cosmetic labeling purposes. CTFA requested we specify which of two crosslinkers listed that we use and specific identification of the comonomer used. I have provided CTFA with a copy of the proposed USP-NF monograph which identifies one crosslinker only but uses the same nonspecific name for stearyl methacrylate. I have indicated the specific comonomer name is proprietary. In conversations with CTFA, they have indicated they may accept the USP-NF proposed descriptions. A decision is not likely to be reached before the end of June.

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3. Code 10C

Compositional and toxicological data on Code 10C was sent to Health and Welfare Canada on behalf of a customer who uses Code 10C to coat PVC polys. Since Code 10C is a very complex mixture it was not possible to give a concise composition. I was, therefore, pleasantly surprised that the Canadian Agency accepted our data and stated they had no objection to its use in the production of food grade PVC bottle compounds.

4. Polycarbophil

BFG has been investigating the manufacture of Polycarbophil. This crossed linked acrylic acid polymer was evaluated by the FDA OTC Drug Panel as safe and effective as a bulk laxative. We have some potential customers for this product. The anticipated volume cannot be produced in our pilot plant. Consequently, BFG will have to have this substance toll manufactured until such time as we have in-house capacity.

I met with the Polycarbophil group to discuss BFG's responsibility in the manufacture and sale of a bulk drug either manufactured in-house or toll manufactured. We have also begun to collect the necessary information to open a Drug Master File for this product.

The NF monograph for Polycarbophil was discontinued in 1985; we will initiate reestablishing this monograph.

5. Rubber matting complaint

We received a TSCA 8(c) allegation concerning our black corrugated rubber matting installed in the lobby and stairway of an office building in Palo Alto, California. A tenant, an M.D., complained that his breathing was adversely effected by the fumes given off by the matting. His problem was described as similar to that of an allergy reaction in the nose, throat and eyes. He further alleged the fumes given off by the matting were toxic and a serious hazard to health.

This is the first such complaint for this product of which we are aware. The composition of the matting is not unusual and no basis can be found for the complaint. We believe the problem is only an odor association. To resolve the problem, marketing has offered to replace the rubber matting with a Koroseal (PVC) matting at no charge.

6. Geon Latex

We are to custom produce a vinyl chloride polymer latex for Unical from their recipe. However, we propose to chemically strip the monomers rather than use Unical's steam stripping. This latex will be used in food contact applications. We also hope to license our chemical stripping technology to Unical in the future. I provided documentation to Unical that our monomer stripping method would not affect the FDA clearance of their product.

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I met with D. E. Weaver to review the FDA requirements for vinyl chloride copolymer latexes. ALTC is trying to develop new vinyl-acrylic latexes for special applications for selected customers. We reviewed all of the various vinyl-acrylic polymers which are acceptable for paper coatings and the various ingredients that may also be used.

7. Flexible Geon Compounds

I attended the Flexible Geon Compound Business Team meeting. I discussed the current FDA PVC proposals and Good Manufacturing Practice for food, drug and cosmetic contact articles.

8. Estanes

I met with the Brecksville Environmental Lab to establish the migration and analytical studies necessary to petition FDA for approval of polyether urethanes for repeated use food contact applications.

9. Butadiene

I reviewed the current FDA status of butadiene containing polymers for both direct (chewing gum) and indirect food additive applications. I tried to predict FDA reaction to the positive animal carcinogenicity studies and how the constituents policy applied. The review was written for Bob Hinderer to present to the IISRP butadiene panel.

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