February 28, 1986

H. W. Dietz

ACTIVITIES REPORT FOR FEBRUARY, 1986

1. PVC

The long-awaited FDA proposal confirming the safety of PVC for food contact applications was published in the February 3, 1986 Federal Register. At the same time, FDA also published the agency's withdrawal of its 1975 proposal which would have prohibited the use of rigid and semirigid PVC food contact articles.

In general the proposal has been well written, containing no surprises. The proposal would amend 16 different existing food additive regulations by specifying residual RVCM levels. In addition, it would establish two new regulations, one for rigid and semirigid PVC food contact articles and one recognizing the prior sanctioned uses of PVC and vinyl chloride copolymers.

Utilizing the constituents policy and an ultraconservative risk assessment, the FDA has set a limit of 5 ppb RVCM for flexible PVC, 10 ppb for rigid and semirigid, 50 ppb for pipe and 50 ppb for vinyl chloride copolymers. The Chemical Group feels that these are achievable levels for most products.

One prior sanction for BFG that I found was not included. This prior sanction by virtue of 1954 and 1956 letters from the USDA is for the use of polyblend resins (a mixture of PVC and acrylonitrile/butadiene resins) in conveyor belts in contact with meat and poultry products. This is a significant business for Chemical and Fabricated Polymers.

I have discussed the FDA proposal with Fabricated Polymers and have met with Chemical several times to explore BFG's options. We have agreed to support the industry comments through SPI, however, we will comment ourselves on BFG's prior sanction.

Once this proposal is finalized, it will open the door again for PVC liquor bottles which should be a significant business for BFG.

2. Good-rite 3125

Ciba-Geigy requested that BFG transfer our current food additive petition for expanded use of Good-rite 3125 to them. The request was made so that Ciba-Geigy would be in closer contact with FDA on the petition. A letter was sent to the FDA requesting transfer fo the petition to Ciba-Geigy. As a result BFG will no longer be involved with this petition. It will be Ciba-Geigy's responsibility to see it to completion.

3. Carbopol

I wrote a comparison of the regulatory and toxicology status of 1,1,1-trichloroethane, ethylene dichloride and methylene chloride. This information is to be used by the Carbopol sales group to try to counteract our competitors' claims of safer nonbenzene Carbopol-type resins.

I again reminded the Carbopol sales group of the published Cosmetic Ingredient Review Experts Panel's article reviewing the Carbomer (Carbopol) resins. The Expert Panel concluded the Carbomers are safe for their current uses. It is evident from this article that only the benzene produced Carbopols were reviewed. I again stressed that this article is not being utilized to its fullest advantage. I believe all current and potential customers should be provided a copy of the article.

4. Good-rite 3126

Good-rite 3126 is being considered as a replacement for BHT in many applications. Migration studies of 3126 utilizing food simulating solvents have been completed. After a written report is recieved, we can proceed with the FDA petitioning process.

5. Estanes

New samples of polyether polyurethane resins have been prepared for migration studies. This was necessary due to a change in Belgie's needs. The new samples contain higher levels of some components as well as new components.

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April 1, 1986

H. W. Dietz

ACTIVITIES REPORT FOR MARCH, 1986

1. PVC

BFG's comments on FDA's February PVC food contact proposal are ready for submission to the Agency. Briefly, we support SPI's comments and bring to the agency's attention BFG prior sanctions for the use of PVC-nitrile rubber blends in conveyor belts in contact with meat and poultry products. Copies of old USDA approval letters (1952-1968) are being submitted to substantiate our prior sanction.

We have let the SPI know that basically we agree with their comments except for their discussion about the migration of VCM into food. SPI bases their discussion on some data from Ethyl which proposes a level at which migration ceases. We feel the data is inconclusive and the discussion is unneeded. We have asked SPI to delete it.

2. Good-rite 3125

We received formal transfer of our food additive petition for expanded use to Ciba-Geigy from the FDA. Thus this petition is now the sole responsibility of Ciba-Geigy.

3. Carbopol

I met with the Carbopol business group to further discuss possible polymerization solvents and recent acrylic acid test results. The solvents of choice, at this time, are ethyl acetate and methyl chloroform. Toxicologically, ethyl acetate would be the solvent of choice.

We discussed the recent paper given at the SOT meeting last month. The paper purported to demonstrate that acrylic acid might be a carcinogen by dermal application. It raised some alarm at P&G because of residual acrylic acid in Carbopol used in toothpaste. The paper was poor, and in many aspects needed to be clarified. Several studies on acrylic acid have shown no carcinogenic activity for acrylic acid; this is the first one. The work for this paper was done some long time ago. It has been speculated that presentation was made at this time so as to justify the author's presence at the meeting.

4. Code 10C

Compositional and toxicological information on Code 10C was sent to Health and Welfare Canada, for DSM, the Netherlands. DSM requested Canadian approval of several PVC resins in which they use Code 10C to coat the polys. Canada requested the composition of Code 10C before they would give approval. Since Code 10C is a very complex mixture, it was not possible to give a concise composition.

5. Estanes

BFG Belgie has wanted to use Hoechst Wax E as a lubricant in Estane polyurethanes for food conveyor belts. Wax E only has FDA acceptance for use in PVC. Hoechst performed migration studies on Estanes containing 1% Wax E. No migration of Wax E was detected at 5 ppb under exaggerated use levels.

Based on these studies and data previously supplied by BFG, Jerry Heckman has given me a written legal opinion that Wax E in this application is not a food additive within the meaning of the FD&C Act. I have discussed this opinion with our Estane group.

6. USDA

The composition of Hycar 1432 was supplied to the USDA at the request of the Dexter Company.

USDA acceptance was received for the use of Good-rite K-XP82N and K-XP83D in boiler water additives, primary steam cooling loops.

7. National Sanitation Foundation (NSF)

Material compositional forms were submitted for Geon compounds for Jean's Extrusions and Sta-Rite Industries to the NSF for evaluation.

8. Latex

On Wednesday, March 26, I received a Quality Management Award from the BFG Latex Business Unit. The award was for gaining broader FDA clearances for Hycar acrylic latexes. The additional broad FDA clearances were the result of an approved petition.

W. C. Bachtel

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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, Carboset 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 Carboset 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.

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.

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 durrent 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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May 30, 1986

H. W. Dietz

ACTIVITIES REPORT FOR MAY, 1986

1. PVC - FDA Proposal

Comments continue to be filed by many individual companies and industry associations on FDA's PVC proposal. In general, these comments are supportive of the FDA proposal except for the residual vinyl chloride monomer analytical method and some other minor issues.

Interestingly, the FDA PVC proposal has generated no opposition from any consumer group thus far.

In response to FDA's request concerning environmental information for incineration of PVC, the Association of Plastics Manufacturers in Europe (APME) has filed comments. These included materials indicating the absence of any relationship between PVC combustion in feed stock and the presence of dioxins in incineration emissions. Another study submitted indicated the relative ease of removing the hydrochloric acid generated by combustion of PVC.

Likewise, the Plasticizers Sector Group of the European Council of Chemical Manufacturers Federation (CEFIC) provided significant information on plasticizers. In reviewing the toxicological literature on DEHP and DEHA, CEFIC concluded that DEHA is not likely to pose a significant hazard to man. Likewise, CEFIC stated that phthalates pose no risk at current exposure levels.

2. No Foul

No Foul is a registered pesticide. Therefore, the Akron plant has been registered as a pesticide producing establishment and has been required to submit an annual production report to the EPA under the Federal Insecticide, Fungicide and Rodenticide Act. I have just become aware of the fact that as of March or April 1985, BFG no longer compounds No Foul in Akron. Rather, a custom compounder, Master Processing in California, has been producing and shipping No Foul under contract to BFG.

Master Processing is not registered as a pesticide producing establishment and therefore is in violation of FIFRA and potentially subject to a $25,000 per day fine (total potential fine could be about $7.5 million). BFG might be liable since we had not informed Master Processing that No Foul was a registered pesticide and the obligatory requirements thereof.

BFG's 1985 total No Foul production reported to the EPA under FIFRA requirements included that quantity produced by Master Processing as well as that made in Akron. Whether this constitutes a false report on BFG's part is not clear.

I have supplied our purchasing agent the EPA registration forms and filing information to forward to Master Processing.

We should have a better grasp of what BFG's obligations and/or liabilities are after Master Processing's registration is complete. This situation would undoubtedly have been avoided if BFG had a strong, effective product stewardship policy in place.

3. ASTM-E-47 Committee Meetings, Symposium

I attended the ASTM E-47 Environmental Effects and Fate Committee meetings and Symposium Sunday, May 4 through May 9. The Symposium and meetings were attended by approximately 200 representatives of government ,academia and industry. The symposium was devoted to aquatic toxicology and hazard assessment. Work progressed on a number of Toxicity Standard Practices with several readied for subcommittee and committee ballot. Work began on new standard practices for additional species. Many of the standard practices developed by E-47 will be required in the future by EPA for testing under TSCA and FIFRA.

4. Geon 110X390

Geon 110X390 is a new ultra low molecular weight suspension resin for CIM applications. The molecular weight is controlled by 2-Mercapto ethanol (2-ME). The 2-ME becomes a part of the backbone of the polymer chain. The question arose as to the FDA status of the resin for food contact applications. Since 2-ME becomes part of the backbone of the polymer, the question was whether this could be considered a PVC homopolymer resin or was it a VC-2-ME copolymer. Resolution of this question was crucial to use in food contact applications.

After consultation with other FDA experts, and consideration of Chem Abstracts, TSCA and other definitions and requirmenets, it was determined that the use of chain transfer agents at very low levels (< 1%) would not result in the resin being a copolymer. Therefore, Geon 110X390 would be considered a homopolymer PVC permitting its use for general food contact applications.

5. Hydrophilics

Calgon uses Carbopol 940 in a liquid hand soap. They noted that the Registry of Toxic Effects (RTECS) listed the human carcinogenicity of polyacrylic acids as indefinite. They also noted the Cosmetic Ingredient Review (CIR) Expert Panel's statement regarding the lack of various data including carcinogenicity, mutagenicity and teratogenicity. It has been explained to Calgon that the RTECS citation is in error and that the CIR Panel's statement was a statement of fact, not a suggestion that the data was needed or should be developed.

Because of the high molecular weight and inactivity of the Carbopol molecule there is nothing to suggest carcinogenic, mutagenic or teratogenic activity, hence no reason to perform such testing.

A "Kosher Food Analysis Form" for Goodrite K-752 has been submitted to the Kosher Overseers' Association of America, Inc. on the behalf of Chaska Chemical Company. Chaska Chemical wishes to use K-752 in a water treatment formulation in the preparation of Kosher foods.

I met with the Carbopol Business Team to determine the Carbopol labeling requirements for the EEC countries. It was determined that the Carbopol resins would have to be labeled as eye irritants which requires use of the Saint Andrews Cross on the label. Although competitors are not labeling in this manner, it was felt the published toxicity information on the Carbomers would compel them to do so if their product is presented as a Carbomer.

Dermick Laboratories has filed an NDA for the use of a topical pharmaceutical preparation incorporating Carbopol 940. However, they wish to substitute Carbopol 1342 for C-940. This would be the first pharmaceutical use of C-1342. I have written a letter to Dermick comparing the results of dermal studies of both Carbopol resins to be incorporated into an amendment to their current NDA. Based on the results of dermal studies on both resins, the FDA should not object to this substitution.

6. National Sanitation Foundation (NSF)

The NSF has sent an announcement concerning their third party program for evaluating drinking water additives (direct and indirect). Participation in the listing and standards development process will have a one-time development cost of $5,000 per company. Additional charges will be made for product testing once the standards have been developed. Participation now will allow input into the standards development.

The information packet has been sent to the product groups to determine if there is enough interest to participate.

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