August 7, 1987

H. W. Dietz

ACTIVITIES REPORT FOR JULY, 1987

1. National Sanitation Foundation (NSF)

I attended the NSF Water Additives Task Group meeting July 1 and 2. The task group reviewed the Peer Review Committee's comments on our proposed product evaluation and toxicological guidelines. In general, the peer review group's comments were supportive and for the most part were incorporated into the guidelines. The rationale document was thoroughly reviewed and rewritten. The revised documents will be sent to the task group for comment and to the NSF Joint Committee for ballot. A tentative meeting has been scheduled to resolve any Joint Committee ballot issues. We expect the Health Effects Task Group's work will be completed by the end of 1987.

The Fibercast Company uses Hycar ATBN as a modifier in their Centricast fiberglass-epoxy pipe. They would like to use this same pipe for potable water applications to reduce the current necessity of producing a separate pipe for this purpose. For potable water applications, the pipe must comply with NSF Standard 14. Hycar ATBN does not have FDA or NSF clearance.

A Fibercast representative, L. Tulle, J. Nolan from the ATBN group and I met with NSF July 27 to agree on studies necessary to get NSF clearance for this use. We will need to perform extraction studies and an Ames test on ATBN as a minimum. I will continue working with the product group on this project.

2. Hydrophilics

I met with several members of Abbott Labs and the Carbopol group July 14 to review Abbott's needs for Carbopol 153. Abbott has settled on Carbopol 153 as the resin of choice for use in a pediatric formulation. They are also looking at other applications involving uses such as vaccines for the non-benzene Carbopols. We discussed their concerns about product consistency, impurities, regulatory and toxicological concerns. The meeting was very productive and allayed many of their concerns. Although Abbott's timetable has been extended about three months, we need to proceed with toxicity testing as soon as possible.

USP-NF questioned the need for a 0.5% benzene limit for the carbomers 934, 940, 941 in light of the fact that Germany has set a 0.2% limit. These carbomers are for external use only. The product group maintains they could not economically live with a 0.2% residual benzene limit.

Using data on the loss of benzene during mucilage make up, measured benzene levels in off the shelf cosmetics known to contain Carbopol resins, skin absorption of benzene and typical external pharmaceutical uses, I made an assessment of possible absorption of benzene from external pharmaceuticals containing typical amounts of Carbopol resin. Under the assumed conditions, it might be possible to absorb approximately 0.22 micrograms or less of benzene per day from such use. This amount is less than 1/1000 of the estimated 250 microgram daily dietary intake of benzene from natural sources and is consequently non-significant.

The Carbopol group is considering the use of low levels of acrylic comonomers to reduce residual benzene levels. A list of 13 acrylic monomers were submitted for toxicological comparison. The list was finally pared to three, namely, n-hexyl methacrylate, 2-methoxyl ethyl acrylate and B carboxy ethyl acrylate. The available toxicity data on these monomers is very limited, as it is for many if not most minor acrylic monomers. However, no data was found to indicate any unusual effects attributed to the above three substances.

Although new Carbopol copolymers containing less than 2% comonomer would not require a PMN under TSCA, they would be considered new copolymers as far as FDA, USDA, USP-NF, CTFA, etc.

3. Carboset Resins

Ten XPD carboset resins were reviewed for their FDA clearance. There are a total of 45 clearances for the ten resins.

4. California Proposition 65

A meeting of the Proposition 65 task force was held July 22. Our outside consultant brought the task group up to date on implementation of the law. To help identify chemicals of concern for BFG on the proposed test of carcinogens and reproductive toxins, we searched the EPEF data base. We found 145 notations. At the request of the product groups, Connie Dillon is running a list of materials for each divisions according to plant location, company I.D. and chemical composition. When completed the lists will be sent to the specified company Proposition 65 representative.

5. No Foul

We have yet another EPA data call in for the tributyltin pesticides. I have discussed the requirements with EPA. We will claim a generic exemption again and file a new Confidential Statement of Formulation form.

6. Adhesives

An industrial hygienist for Mack Trucks questioned our warning statement on the product bulletin for Plastilock 904. As written, the warning statement stated that excessive exposure to vapors might cause serious personal injury or death. This statement, although appropriate for organic solvents, is totally inappropriate for a solid hot melt adhesive such as PL-904. We had not reviewed or had not been asked to review this literature before release.

To help Mack Truck with their employee relations, I wrote a letter explaining why the statement was not appropriate and suggested warning statements appropriate for PL-904. I requested the product group change the product bulletin to remove the current precautions and replace them with those I wrote.

7. Geon compounds

We have had several Geon compound, rigid and flexible, tested to comply with USP Class VI biological tests and cytotoxicity tests. I have reviewed the test results as related to the chemical composition with the product group. In general, we find the compounds highly plasticized, particularly with phthalates which will not pass the cytotoxicity and USP tests. We have also identified other ingredients which appear to cause failure. I am working with the group to develop and evaluate alternates.

8. USDA

We have received USDA letters of acceptance for the use of Geon 8700 white 119 and Temprite AF-3506 in incidental contact with meat and poultry products.

We have requested USDA acceptance for the use of Hycar 1577 in conveyor belts and for Geon 580X119 for a glove coating.

9. Canada

I supplied the Canadian Agriculture Department with the composition of Estane 454600 white 126 at the request of

Ammerall Company of Holland. Ammerall wishes to obtain Canadian clearance for the use of Estane 54600 white 126 in conveyor belts.

W. C. Bachtel

jp 0804-2

cc: R. K. Hinderer

November 24, 1987

H. W. Dietz

ACTIVITIES REPORT FOR NOVEMBER, 1987

1. National Sanitation Foundation (NSF)

I attended the NSF Joint Committee (J.C.) for Drinking Water Additives in Alan Olson's place. The status of NSF Standards 60 (direct additives) and 61 (indirect additives) was reviewed. Standard 60 is scheduled for publication December, 1987 and Standard 61 in August of 1988.

A number of issues were discussed and J.C. recommendations were sent back to the task groups for consideration. Briefly, some of the issues discussed were:

a. Evaluation dose vs. maximum dose as applied to direct additives (coagulants, disinfectants). After lengthy discussion the definitions were changed to reflect real world conditions.
b. Teratology testing requirements were approved.
c. Acute exposure toxicity requirements as they apply to initial high solvent values were discussed and the general approach approved.
d. Testing water characteristics, particularly test water pH, were discussed at length. A straw vote showed 14 in favor of the original 5-10 pH range and 4 for the proposed 6.4 and 9.4 pH. pH is particularly important to the metal products people.
e. A microbial growth support test was discussed and will be incorporated by each task group as needed.
f. A normalizing concept for devices and coatings to project results from exaggerated testing to real world conditions was discussed and supported by the J.C. There was also a proposal set forth by the mechanical devices group to "grandfather" certain generic materials (mostly metals) which would not require evaluation testing.

There was additional discussion on certification of testing labs and products lists to be kept by AWWA. AWWA will not accept manufacturer self-certification. It was noted that California will require certification almost immediately and about 1/3 to 1/2 of the states within five years.

2. Hydrophilics

Our Swiss consultant, Dr. Leimgruber, has outlined a program to obtain European clearance for polycarbophil as a bulk laxative and antidiarrheal. The total cost for country-by-country registration and his services will be about $70-80,000. It will take 1-2 years to complete the project. The Hydrophilics group will include funds for the project in their 1988 budget. The required time period will coincide with our ability to supply polycarbophil to the European market.

Calvert City is completing the monograph testing on the sample of Carbopol 940 supplied to USP-NF as a reference sample two years ago. They were unable to locate a retained sample of Carbopol 1342 for the same testing. USP-NF will return enough of the sample of C-1342 for the required tests.

The Mineral Spirits Carbopol products were evaluated for their FDA clearance for use in contact with foods. The mineral spirit solvent used in these products severely limits their clearance to use only under two FDA regulations: the Adhesive and Defoaming Agents Used in Coatings regulations.

3. Polyurethanes

BFG has finished our analysis of the polyetherurethanes extracts for MDA. Dow and DuPont have yet to complete their portions of the study. However, a very preliminary draft of a petition to FDA for clearance of these polymers in repeated use articles has been completed and will be reviewed with Dow.

4. Geon Vinyls

We have requested USDA acceptance for the first fiberglass reinforced PVC compound, Fiberloc 803GR10, for use in a scale housing for Hobart.

Scott Paper wants to use Geon 460X46 in a consumer product where skin contact could be a problem. I have sent a copy of the human repeated patch tests to Scott. In addition, we are having cytotoxicity tests run STAT on films of 460X46. Successful completion of these tests and acceptance by Scott Paper could result in a million dollar/year account.

The Gary Chemical Company wants to use Geon 30 and Geon 102EP in a biomedical application. For this application they required certification of the prior sanctioned status of these PVC resins in food contact applications. At the request of the Vinyls group, I certified in writing that both Geon 30 and 102EP were indeed prior sanctioned for food contact applications.

5. Biomedical Safety Evaluation

Bruce Cady requested that I make a presentation to Market Development group on biomedical product safety evaluation. Since the meeting is scheduled during my forthcoming absences, I prepared a length summary of many of the considerations and testing techniques that must be evaluated in establishing a testing program for biomedical products be they band-aids, pacemakers, catheters or any one of a myriad such products. Mr. Cady felt the summary covered the subject very well and brought to attention the complexity of these evaluations, i.e., that one or two tests do not cover or are not appropriate for all situations.

6. Computer Access

I now have access on my CRT to the SP&C, E&L and Vinyl Divisions' recipe and raw materials files. This has saved much time in obtaining the required information for evaluation of FDA status, requesting NSF listing and USDA clearance of various BFG products. I no longer need to contact three to four or more people to obtain the necessary information sometimes requiring days or weeks to complete.

W. C. Bachtel

jp 71124-6

cc: R. K. Hinderer

March 31, 1987

H. W. Dietz

Activities Report for March, 1987

1. Val Vista Reservoir

The United States Fidelity and Guaranty Company is suing BFG, the City of Phoenix, McCarthy Western and James M. Montgomery, Consulting Engineers, over loss incurred due to alleged improper installation of the Val Vista reservoir liner. I was briefed on the suit by the lawyers representing BFG on March 2 and my deposition was taken on March 5. Mr. Thorpe, representing McCarthy Western, used the entire day. The other attorneys reserved the right to question at a later date. All in all, the deposition seemed to go smoothly.

2. Estanes

FDA has acknowledged receipt of the letter requesting a pre-petition meeting on the BFG, Dow and DuPont proposal to amend 21CFR 177.2600 to include polyether polyurethanes for use in repeated food contact articles (conveyor belts, hoses, etc.). After FDA's review, they will contact us to arrange a meeting to discuss the proposals.

Both NIOSH and NTP have agreed to delete Estane 5703 as a synonym for urethane (ethyl carbamate) from the next issue of the Registry of Toxic Effects of Chemical Substances (RTECS) and the Fifth Annual Report on Carcinogens. Ethyl carbamate is commonly called urethane and has received widespread media attention lately as an impurity in alcoholic beverages. IARC has classified urethane as an animal carcinogen. There has been a lot of confusion over urethane vs. polyurethane resulting in inquiries from customers, part of which came from the incorrect listing of Estane 5703 as urethane.

I have requested USDA acceptance for the use of Estanes 54610 green 515 and 54600 green 515 in the fabrication of conveyor belts for use in federally inspected meat and poultry processing establishments. USDA acceptance was sought at the request of Habasit, Inc.

The FDA status of Estanes 5740X76 and 4143-021 were evaluated for J. Udo, BFG, Belgie.

3. Hydrophilics

Carol Hartstein, Director of Quality Assurance, Alza Laboratories, performed a quality audit of the Carbopol EX-120 manufacturing facilities and recordkeeping at Avon Lake. Ms. Hartstein felt comfortable with our operations and believed BFG realized the requirements for making a pharmaceutical product. Alza plans to use Carbopol EX-120 in a time release cattle bolus application. Prior to Ms. Hartstein's March 11 visit, I had performed a GMP audit and made several recommendations that were effected before Alza's audit.

A question arose as to whether Carbopol 956 (new non-benzene resin) should be labeled "for external use only" or "for internal use." On the basis of the similarity of C-956 to the other benzene polymerized C-900 series resins and with no toxicity data to the contrary, I recommended the label contain no use indications. Rather, until toxicity data is generated which would so indicate, the customer should be advised to evaluate his own particular use.

Dan River, our toll manufacturer for polycarbophil (Carbopol EX-83) is now registered with the FDA for this product. Dan River has been unsuccessful at producing an acceptable product to date. Consequently, polymerization and washing are being done at ALTC after which the product is sent to Dan River for drying, grinding and packaging. I have reviewed the process with ALTC and discussed the additional steps necessary under these conditions to insure adherence with Good Manufacturing Practice (GMP).

Bob Hinderer and I met with the Carbopol group to recommend toxicity testing needed for the new non-benzene polymerized Carbopol resins, Carbopol EX-119 in particular. We have recommended absorption studies, 30-day and 6-month feeding studies in rats and dogs. Once some commitment is obtained for the expenditure of the approximate 300 to 375 thousand dollars, definitive protocols will be developed. Since Abbott's timetable for their pediatric product containing Carbopol EX-119 is dependent on our progress, I am keeping their toxicologist up to date on our progress.

4. PVC Resins

We have been using Abex 33S, a proprietary emulsifier, in many PVC resins used in medical devices and food contact applications. FDA clearance of the PVC resins containing Abex 33S was based on written assurance from the supplier that this emulsifier had FDA acceptance for such use. Recently we have been informed by the supplier that according to their current interpretation Abex 33S does not have FDA clearance. I met with the ALTC PVC group and the supplier to determine a course of action to follow.

Alcolac has written FDA requesting an advisory opinion as to the clearance of Abex 33S. Meanwhile, BFG will look for a suitable acceptable replacement. We will continue to sell the product to the same market unless FDA provides a negative response. Should this happen we will have to either introduce a suitable emulsifier or withdraw the affected resins from the medical/food contact market. Should the FDA respond negatively, it will be necessary for the supplier to petition FDA for the desired use in which case clearance may not be granted for one to two years or longer. Alcolac is to keep me up to date on their dealings with FDA so that we may take appropriate timely actions.

5. Geltrol

It has been proposed to substitute toluene for benzene as the solvent in the production of Stabilox, the major ingredient in Geltrol. Concern was expressed that this substitution might have an effect on the FDA clearance of Geltrol. I have reviewed the proposed solvent change. It will have no effect on the FDA clearance of Geltrol.

Goodrich used Geltrol in most of the Ameripol SBR's. The new UGT management wants to replace Geltrol with BHT. The switch to BHT could mean a loss of two million dollars in sales.

A question has arisen as to the future FDA status of BHT in light of the carcinogenic effects attributed to it in a recent Danish study. According to contacts close to the FDA, the agency is unlikely to take any action to restrict the use of BHT for at least two to three years.

I have passed this information on to R. Taylor along with a review of the current FDA status of Geltrol and BHT.

6. No Foul

We have received a "Data Call-in Notice for Information on Generic Data Exemption" for No Foul. We are required by the EPA to supply certain information and a certification of the accuracy of the information supplied. Failure to supply the required information will result in cancellation of registration. Notice is also given that products eligible for Generic Data Exemption will be required to submit certain product test data at a later date.

I am working with B. Morris, Plant 6, to provide a suitable reply.

7. NSF

Three Marietta compounds were submitted for National Sanitation Foundation review at the request of Jean's Extrusions. These are for refrigerator gasket and freezer panel use.

8. Latexes

Four Hycar and Goodrite latexes were reviewed for their FDA status. They were Hycars 1872X6, 1562X160, 2600X300, and Goodrite 1800X73.

W. C. Bachtel

jp 0331-1

2221204

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.

W. C. Bachtel

jp 0505-1

December 30, 1986

H. W. Dietz

Activities Report - December, 1986

1. Carbopol

The Calvert City Carbopol facility was inspected by the FDA on December 11, 1986. The inspector found the plant to be totally in compliance with Good Manufacturing Practice (GMP) guidelines. However, he questioned our practice of reprocessing off-spec material. He suggested this "gray" area should be reviewed to verify compliance with GMP. Because Carbopol is a bulk drug ingredient of a specific chemical identity (i.e., not a finished pharmaceutical in dosage form) such reprocessing is acceptable so long as the end product meets all NF specifications.

2. Polycarbophil

Plans are moving forward to manufacture and market calcium polycarbophil, USP (Carbopol EX83). The product will be toll manufactured for BFG by Dan River, Inc. In preparation for this activity, forms for FDA-GMP compliance have been reviewed and accepted. Also, in compliance with the Drug Listing Act, the necessary FDA forms for Drug Product Listing are being completed for submission to the FDA.

One problem has occurred. Divinyl glycol (the crosslinker) cannot be found on the TSCA inventory. We have asked our supplier to verify its TSCA status before we can go further.

3. SPI - Food, Drug and Cosmetics Packaging Materials Committee (FDCPMC)

On December 2-3 I attended the SPI FDCPMC semiannual meeting. Various current FDA regulatory activities including the SPI Threshold of Regulation petition and the FDA PVC proposal were discussed. Current activities of the EPA and OSHA impacting the FD&C packaging interests were also discussed.

Current activity on the FDA PVC proposal has been caught up in a quagmire of comments concerning the environmental impact of the proposal. Numerous comments from consumers, and environmental groups questioning incineration and

waste disposal must be resolved. SPI is submitting comments to counter the alleged unfavorable impact. Meanwhile, the BTAF will not approve PVC liquor bottles until FDA has issued a final PVC regulation. This appears to be a long way off.

4. CMA - Rubber Additives Panel

On December 18, I attended the CMA Rubber Additives Panel meeting. Past achievements and goals for 1987 were discussed including appropriate response to the forthcoming EPA test rule for MBTS.

I presented a brief report on the NTP studies to date on 1,2,dihydro-2,2,4-trimethylquinoline.

5. PVC Potable Water Bottles

Sparlets, a division of McKisson, is interested in the use of PVC bottles for potable water. In preliminary extractions vinyl chloride monomer (detection level 0.25 ppb) could be detected in the water contained in 1.75 liter PVC bottles. However, because of California Proposition 65, it is uncertain whether this level of detection is low enough to avoid the labeling provisions contained in the law.

I have discussed this situation with representatives of the California Department of Health. Some of them seem to be as confused as everyone else about the ramifications of Proposition 65. One person in the bottled water program felt that if the container complied with U.S. FDA requirements, it would be acceptable. Some mineral waters are being imported in PVC bottles presently.

We are planning an extraction study on a number of bottles to simulate a 6-month shelf life. If no VCM can be detected in these at a level of less than 0.25 ppb we should be able to assure their compliance with Proposition 65. The current California recommended MCL for vinyl chloride in potable water is 2 ppb.

This could be a significant market for rigid Geon compounds.

6. KoroKlear Vinyl Strip and Sheet

The reformulated KoroKlear Vinyl Strip and Sheet compound has received a favorable review by the National Sanitation Foundation (NSF). NSF has requested compound samples for qualification extraction testing. Apparently my last letter to the NSF contact with a copy to their CEO and Vice President has gotten some positive results.

The minor reformulation of KoroKlear to overcome NSF's objections has necessitated resubmittal of the formulation to USDA for their acceptance.

7. No Foul

The annual EPA Pesticide Report forms for No Foul Rubber and ProMac have been received. These have been forwarded to the appropriate BFG persons for completion.

8. Estanes

The formulation of Estane 58277 has been submitted to the EPA, Office of Drinking Water as requested by Deerfield Polyurethanes Co. Deerfield has a potable water application for Estane 58277 film.

W. C. Bachtel

W. C. Bachtel

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