August 30, 1985

R. A. Guyton, M.D.

Subject: Environmental Health/Industrial Hygiene/Toxicology
Activity Report - August 1985

1. At the plant's request Mr. Katzenmeyer visited Marietta to review requirements for labeling and material safety data sheets under the OSHA hazard communication rule. The plant has requested assistance in preparing data sheets and labels for chemical materials shipped to other BFG plants and outside customers. A plan was devised to initiate this project.

2. Dr. Dietz, Tom Krena and Mr. Katzenmeyer met with NIOSH representatives involved with the health hazard evaluation at Fort Wayne. The local union had requested NIOSH to investigate a possible excess of cancers occurring in the mill and tube area. NIOSH efforts to date resulted in a letter to the union suggesting a cancer excess based on the cases reported (which were never verified for accuracy). NIOSH was made aware that BFG regarded the letter as misleading and we were surprised that the cases were not verified, especially since the preliminary information had already been done by BFG. It was agreed to provide NIOSH with information from the medical surveillance system concerning available medical diagnoses, updated industrial hygiene measurements, and copies of death certificates for the individuals listed by NIOSH.

3. Efforts to obtain EPA approval of Estane 54600 for use in a potable water pipe replacement system are continuing. We are working with Shell and Insituform on this project and plan to submit all available information to EPA within the next two weeks. One of the problems we face is that we do not have any toxicology information on the product. Because this Estane undergoes hydrolysis in contact with water, we are sure that EPA will have many questions. In preparation, Dr. Hinderer has developed a testing program to address the health areas of concern. This supplemental information will be submitted to EPA as soon as it is available.

4. We learned that EPA plans to require manufacturers and importers to conduct health and environmental effects testing on MBT, MBTS, OBTS and BBTS. These studies are expected to cost approximately $5MM.

   We are presently working with the CMA Rubber Additives Panel to try to eliminate any unnecessary testing and to be ready to comply with the final test rules. Once a rule has been finalized, the subject companies have five years to complete the testing. All are subject to $25,000/day fines for not meeting the deadlines. Because some of these studies take 4-5 years to complete, early planning is needed to guard against unforeseen delays.

5. The Cure-rite 18 male dominant lethal and reproductive studies are complete and we are waiting for the final reports to be submitted. No dominant lethal or reproductive effects have been observed.

6. The Vinyl Institute studies at Southwest Research are proceeding satisfactorily. New analytical procedures are now in place and we expect that the final baboon exposure to HCl will be completed within the next two weeks. SWRI informed us that the first exposure of rats and guinea pigs to HCl will occur shortly.

7. A voluminous file pertaining to FDA petitions and toxicological data on Goodrite 3114 and 3125 was delivered to the Chemical Group, polymer chemicals division. The material will be edited to remove confidential information before transmittal to Ciba-Geigy. This action necessitated copying over 1,000 pages of material.

   Ciba-Geigy has contracted for Brecksville to develop the data necessary to answer FDA's questions on the 3125 petition. We will submit the data to FDA when complete. If FDA has additional requests, depending on their complexity, we will either answer them, turn the petition over to Ciba-Geigy, or withdraw the petition without prejudice.

8. We have had some preliminary response from USP regarding our recent Carbomer monograph proposals. As a result, we will not pursue deletion of the heavy metals limit. Initial USP reaction to our GC-mass spec method for total volatile organics has not been favorable; however, we have had not formal report from the full USP standards committee. If this method is not accepted, we will likely drop the matter. Our offer of another face-to-face meeting to settle differences was seen as premature by USP.

9. The recent Consumer Product Safety Commission's (CPSC) Chronic Hazard Advisory Panel's (CHAP) draft report on DEHP has caused concern about the use of this plasticizer in food, drug, and cosmetic applications. The CPSC/CHAP report has no direct effect on FDA's jurisdictional area. FDA is studying the situation, but intends to move cautiously. However, the CHAP report caused undue panic in the Chemical Group and one customer, Alcoa. Alcoa overreacted when the FDA sampled cap liner material for migration studies. Alcoa was pushing an unreasonable time table to replace this plasticizer in bottle cap material. Mr. Bachtel has succeeded in calming the situation somewhat. He is working with Cleveland and Avon Lake to develop substitute compounds; however, there are few alternate FDA acceptable plasticizers available and these may present technical problems.

10. Mr. Bachtel reviewed statements relating to toxicity and safety made in an ad for Carbopol 934-P in Pharmaceutical Technology. The statements had been taken out of context or were based on very old studies not meeting todays standards. In short, they were not supportable. He developed substitute wording; however, it was decided to pull the ad until a suitable alternative could be developed. The Carbopol group will clear all such ads with us in the future.

11. We have had an allegation of severe skin and eye irritation and nausea due to a buffing operation of our tank lining material 1020 HT Triflex. This is the first such reported incident with this material. Based

on the recipes, it is difficult to explain what may have caused the adverse effects reported. Mr. Bachtel discussed the situation with our people (H. Geiger) and with the customer, Rubber Linings, Inc., Harvey, La. (Mr. Wayne Ehert) and requested a sample of the material used for analysis to see if the culprit can be identified.

12. IPD plans to test market four Tremco (Canada) sealants and caulks in the Buffalo, N.Y. area for consumer use. Review of the current Tremco labels for their precautionary and first aid statements found them entirely inadequate and grossly deficient according to CPSC requirements for such products. Mr. Bachtel relayed the required hazard precautions and first aid statements to IPD and affirmed that they were necessary, even in a test market situation.

13. Japan will not permit the use of No Foul with tributyltin oxide (TBTO). They will, however, allow the use of a No Foul formulation using tributyltin fluoride (TBTF) as the antifouling agent. Mr. Bachtel confirmed with the EPA Office of Pesticides that BFG would not have to register as a pesticide producer for such a product so long as No Foul incorporating TBTF is solely for export. Thus, we will not have to comply with all the costly reporting, registration, and data requirements of FIFRA. Mr. Bachtel informed the No Foul marketing group of these facts.

14. The Chemical Group, through A. Olson, has again expressed interest in obtaining FDA acceptance of CPVC resins for food contact applications. We learned of their interest from P. Zakriski after Olson requested cost estimates for extraction studies. No defined action plan was proposed.

    In a memo to Mr. Olson, Mr. Bachtel reviewed the current FDA requirements and proposed changes for indirect food additive petitions and noted the possible difficulties of obtaining clearance for a product such as CPVC that could potentially have residual levels of three carcinogens: vinyl chloride, chloroform and carbon tetrachloride. Mr. Bachtel stated this department would handle such a petition and advised an early meeting with FDA before starting any work.

15. The EPA published a Notice of Decision not to regulate VDC as a potentially toxic air pollutant (FR Aug. 13, 1985). They concluded that the overall weight of evidence for carcinogenicity is not sufficient to warrant regulatory action. The CMA VDC panel intends to submit supporting comments.

16. We received a letter of acceptance from the USDA for seven Geon resins submitted for Plastomerics, Inc. We also received similar letters for Hycar 1312X22 and Geon 110X337 from the USDA and Canadian Agriculture Department. The latter were submitted in behalf of Chemprene.

17. Dr. Hinderer attended a meeting of the IISRP Environmental Health Committee. The OSHA hazard communication rule was a major subject of discussion. The committee decided that a meeting with OSHA should be arranged to discuss some of the compliance problems faced by the SBR and tire industries and to obtain some clarification. The group

reviewed the considerable number of toxicological evaluations underway and noted that regulation of butadiene by OSHA and EPA has slowed somewhat. However, EPA is expected to officially refer butadiene to OSHA and propose ambient air regulations by the end of the year.

18. The Chemical Group has asked our assistance in evaluating the health effects of several chemicals (and adducts) which are potential candidates for use in reducing acrylonitrile levels in latex products. The latex group does not want to end up with an additive whose adducts are just as toxic as the acrylonitrile. A review of the literature and mutagenic screening is planned.

19. All job codes for Salisbury have been redone and correctly entered into MSS. All individual employee records have been corrected and will be submitted when new division codes and budget group codes are assigned to EPG locations.

20. All death certificates, Metpath tape corrections and disabilities are current to date in the system.

21. Mrs. Wallace entered 4,807 records into the system this month.

H. W. Dietz

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