April 3, 1985

R. A. Guyton, M.D.

Subject: Environmental Health/Industrial Hygiene/Toxicology Activity Report
March 1985

1. Exposure of baboons to 500, 5000 and 11,500 ppm HCl have been completed. Because of concerns about the delayed onset of respiratory disease and because of questionable findings in one animal at 5000 ppm, we plan to recommend to the Vinyl Institute medical committee that all baboons be held for one year. Efforts are now underway to assemble and test out plethysmographic methods for rodent pulmonary function evaluations.

2. Dr. Hinderer met with Dr. Jachimcyzk, the Houston medical examiner, to review the autopsy data and discuss the Birky/FFS report on the Westchase Hilton fire. Because of his personal health problems, Dr. Jachimcyzk was unable to make any commitment to any efforts to counteract the FFS report. Therefore, we have decided to pursue this subject with Dr. Cleveland, Cincinnati coroner. Although, Dr. Cleveland has a short-term commitment, this appears to be the most reasonable compromise.

3. Reproduction and dominant lethal studies with Curerite 18 have begun. A site visit progress check is planned for mid-April.

4. Drs. Johnson, Riddle and Hinderer met with NSF and their consultant, Dr. Hartung, to inform them of the results of mutagenic evaluations of the orange dye which we are attempting to get approved for use in CPVC pipe for sprinklers. NSF gave verbal approval for continued interim use of the batch of orange dye which was not mutagenic. They also agreed that further efforts should be undertaken to identify the factor responsible for mutagenic activity in the original batch. The need for a 90-day feeding study was discussed. The product group has been advised and we are awaiting a decision on who will fund the study.

5. Toxicological evaluations of Goodrite XNP-5 are now complete. This information will be used to support EPA/FIFRA biocide registration. We expect to submit the registration package to EPA in April.

6. We are waiting for a sufficient quantity of Goodrite 3150 to be produced for toxicological evaluations. Toxicity studies will begin as soon as samples are received.

7. Toxicological evaluations of Biofilm are continuing. We are conducting a battery of studies, including extensive testing, to determine the reason for cytotoxicity observed in the in vitro MEM elution assay. The results of the MEM assay appear to parallel effects noted in wound healing studies conducted by Johnson and Johnson.

8. The EPA Office of Toxic Substances and the Cancer Assessment Group have prepared risk assessment documents (occupational and environmental) on 1,3 butadiene. We are working with IISRP to comment on gross inaccuracies, deficiencies, and overestimates of risk.

9. An update of the original IISRP/Johns Hopkins epidemiology study is proceeding. Some administrative problems in obtaining death certificates have occurred; however, a draft final report is still projected to be available this fall. This work is very important since it will strenghthen the data amd make it even more difficult for the agencies to ignore the human experience.

10. We continue to participate in the Kemper lawsuit. Assistance in responding to discovery requests was provided.

11. We received a preliminary draft regulation for review and comment in response to our petition to amend 177.1010 "Acrylics and Modified Acrylic Plastics". The FDA agreed to amend 177.1010 to permit the regulated acrylics to be used as components of food contact articles as requested. The agency went further than our original petition and have proposed amending 176.170, the paper and paperboard regulation, to specifically include reference to the acrylics listed under 177.1010. We responded affirmatively to the draft regulation. From past experience, the final regulation should be published in the Federal Register in 2-3 months.

    Approval of this petition will greatly expand the number of Hycar latexes that can be used for a wide variety of food contact applications such as paper and paperboard coatings, can enamels, sealing gaskets, food filters, etc.

12. We received a preliminary draft regulation for review and comment in response to our petition to permit additional uses of Goodrite 3114 in olefin copolymer food contact articles. The FDA has proposed to permit the additional uses as requested. We made a positive resonse. Publication in the Federal Register should be within 2-3 months. This petition was originally submitted in response to Shell's need for a Tupperware compound.

13. A petition to amend 178.2010 to permit additional use of Goodrite 3125 in olefin copolymers is being prepared and should be submitted within the next 1-2 weeks. Whether FDA will approve the petition as submitted is questionable due to excessive migration in the fatty food simulating solvent. We may have to amend the petition at a later date.

14. Work is progressing to obtain the additional data needed to resolve the USP-NF monograph on the various Carbopol resins. We are trying to include specifications and tests to define and characterize Carbomer tightly enough so that only the Carbopol resins will be included in order to reduce competition.

    The Cosmetic, Toiletry and Fragrance Association has adopted polyacrylic acid as the generic name for Carbopol 907 rather than Carbomer as requested.

    A draft NTP report of an inhalation study on methylene chloride at Battelle tentatively condludes that "it causes tumors - or cancer - in male and female mice and female rats and there is some evidence that it causes cancer in male rats". In a Washington Times magazine article (3-27-85), an FDA spokesman indicates the agency has little concern over present use of methylene chloride to decaffinate coffee. Methylene chloride has been proposed as a polymerization solvent for Carbopol.

15. We resolved several questions concerning the IITRI extraction report on polyether Estanes. Mr. Bachtel made an FOI request for the FDA Cancer Assessment Group's document for methylene dianiline. With this document we should be able to determine our chances of successfully petitioning for use of the polyether urethanes for repeated use articles.

    We supplied the EPA Office of Drinking Water with the formulation of Estane 54640 and its FDA and NSF status as it pertains to food contact and potable water. Based on an evaluation of the data, EPA has approved Estane 54640 as a 10 mil coating on the inside of liquid storage tanks to hold potable water for the Army. The information was supplied at the request of ILC Dover, manufacturer of the tanks.

16. USF&G, the bonding company, is suing BFGoodrich over the Val Vista reservoir lining project. A meeting is to be held April 11 to determine the course of action BFG should take.

17. A potential customer contacted Mr. Bachtel about some PVC resins for use in products under USDA jurisdiction. He stated he had planned on using Formosa resins, but the USDA would not accept them. The USDA referred him to Mr. Bachtel because they have given approval for several BFG PVC resins. Mr. Bachtel referred the customer to the PVC marketing group. It is interesting that USDA made the referral; they normally do not refer or endorse manufacturers.

18. We received a letter from the FDA confirming our interpretation of the regulations and policy on registration of the Calvert City Carbopol plant. BFG is not required to register the plant as a drug manufacturer; our registration is voluntary.

    Mr. Bachtel informed the Carbopol group and has recommended we continue voluntary registration and agressively use this in our sales efforts. So far, the Carbopol group agrees to continue the registration.

19. Dr. Johnson assisted our attorneys in taking the depositions of three American Motorists Insurance Company's medical expert witnesses.

20. Mr. Katzenmeyer attended a round table discussion on butadiene sampling and analysis sponsored by the IISRP and hosted by Uniroyal. Representatives from several producers and users were present. There was considerable variation in methods used by various companies as well as the extent of validation of their procedures. There was a concern that additional work needs to be done and that the committee would meet again to follow-up on some of the issues identified at the meeting.

21. Mr. Katzenmeyer visited the Tremco, Toronto facility at their request. In response to provincial health regulations, the plant is interested in establishing a more comprehensive industrial hygiene program. He was asked to review their operation and to provide guidance as to priorities and content of such a program. The plant is to begin implementing activities required by the Ontario asbestos regulation. This was a most enjoyable trip. The people at Tremco were very professional, interested, and involved in addressing worker health. They appeared receptive to a number of suggestions made by Mr. Katzenmeyer.

22. Mr. Katzenmeyer is working to familiarize himself with BASIS and is in the process of reviewing OSHA hazard communication requirements to see how this system can be used to assist the product groups in complying with the regulation.

23. We now have a reasonably accurate job history for the Louisville plant. Industrial hygiene data from the Chemical Group is being coded and entered into MSS. A trial report was run and it appears that this project can be accomplished.

24. Mortality ratio reports, including 1984, have now been successfully generated for all plants. Three attempts were necessary before all programming corrections were identified and completed.

25. A medical scheduling program was generated for all participating locations. Port Neches has now started using this program.

26. Mrs. Wallace entered 6,523 records into the system this month.

H. W. Dietz

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