March 6, 1985

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

1. The three month pulmonary function evaluations of the three baboons exposed to 5000 ppm HCl is complete. Two of these animals appeared to be normal, but one showed some pulmonary function changes of questionable significance. Whether this is an incidental finding in one animal, or an indication of future trouble for all three remains uncertain. The planned 6 month pulmonary function testing should clear up this point. Since exposure of a single animal to 11,500 ppm HCl produced significant pulmonary changes at day three post-exposure, plans have been made to proceed to the 500 ppm dose level. Following this work, we will hold off an any further baboon studies until we have some rodent data. However, we have notified SWRI that we want to keep the baboons for one year and conduct pulmonary function analyses at 6 and 12 months.

   We received the proposal from SWRI for developing a combustion system that will allow continuous generation of HCl from PVC. Copies have been sent to the Medical Committee for their review.

2. Dr. Hinderer arranged a meeting with Dr. Jachimcyzk, the Houston medical examiner. We hope that Dr. Jachimczyk will agree to a publication to counteract the Birky/ FFS report.

3. All corrections in the 8-volume final report of the effects of long-term exposure to Curerite 18 have now been completed.

4. Final arrangements have been made for the initiation of the dominant lethal/ reproductive studies with Curerite 18. Animals are now in quarantine and exposure is scheduled to begin in mid-March.

5. Toxicological evaluations of Carbopol 1342 have been completed. A summary of this work has been prepared for distribution to potential customers.

6. The Chemical Group has informed us they are interested in marketing Goodrite 3150 in the EEC. Since this is a new product, we have provided information on the toxicology studies that will be needed to meet the EEC 6th Amendment premarketing requirements. We noted that some of the tests are different than those used in the U.S.

7. Dr. Hinderer attended a meeting of the CMA Rubber Additives Panel. Existing data on the environmental fate of MBT and MBTS was discussed. Since the EPA is considering testing requirements for several rubber additives, preparations for data gathering and meetings with EPA and NTP were discussed.

8. The new OSHA labeling law requires labeling of materials according to their hazard(s). In order to assist the Chemical Group in complying with this regulation, we met with Chemical Group representatives to determine whether Carbopol needs to be labeled to note that it contains benzene and that it represents a carcinogenic hazard. After a review of all the data, we concluded that Carbopol does not pose a carcinogenic hazard and does not require labeling as such.

9. We continue to assist the legal department in answering interrogatories.

10. There has been no further work on the acrylics petition. The second review period expires at the end of March.

11. On February 5, P.Smith, P.Zakriski and Mr. Bachtel met with the FDA to discuss additional clearance for Goodrite 3125. They discussed the migration studies in low density polyethylene. Based on these studies, the amount of 3125 which could migrate into food is borderline without additional toxicity studies. FDA advised us to submit a petition for the desired clearance anyway. If the current toxicity data will not support the clearance requested, a lesser amount will be proposed. A petition will be submitted within the next month.

13. Mr. Bachtel received an advance Federal Register notice of filing our petition for additional clearance for Goodrite 3114. This notice was delayed for a number of reasons, none of which had to do with the quality of the petition. At the February 13 FDA meeting we were told that the 3114 petition was moving through the process without problems.

    When questioned about the effectiveness of using a consultant to deliver the petition, the FDA indicated it made little, if any difference. In fact, they indicated that under certain conditions it could be a hindrance.

14. We received the migration report from IIT Research Institute on the polyether-urethane compound. The report is confusing and falls short of the original proposal. Very low levels of methylene dianiline (MDA) are reported to migrate to food simulating solvents under the test conditions. Based on a repeated use condition, the levels of MDA that would migrate into food are in the ppt level.

    The FDA felt this could be dealt with under the "Constituents Policy". Much additional work will be required before a petition can be submitted.

15. An FDA inspection of the Calvert City plant went smoothly. The inspector commented that the plant was complying very well with good manufacturing practice (GMP). He also questioned the need to be registered as a drug manufacturer. We are trying to determine if we are compelled to register by FDA or if registration in BFG's case need only be voluntary.

    On February 28, Messrs. Koebel and Bachtel met with USP-NF to resolve our differences on the NF Carbomer 934P monograph and the proposed monographs for other Carbomers. The meeting was very successful. As a result, we expect to have published within 1 to 1½ years a family monograph on the Carbomers, including new copolymers.

16. Polycarbophil is a copolymer of acrylic acid crosslinked with divinyl glycol. The FDA over the counter panel (OTC) classed Polycarbophil as safe and effective for a bulk laxative and antidiarrheal agent. BFG has set up a pilot program at Avon Lake Technical to produce Polycarbophil. Mr. Bachtel inspected the area with the engineer in charge and made recommendations to comply with GMP's for such a product.

17. We received USDA acceptance from both the Chemistry Group and the Equipment Group for Novitane FG 95A conveyor belting. We also received USDA acceptance for Goodrite KXP74 and KXP80 for use in egg wash and boiler water treatment formulations. Goodrites K738X1, K759, K758 and K739 were approved for use in egg wash formulations.

18. Mr. Greg Bednarcik (General Engineering) and Mr. Katzenmeyer met with representatives from the National Institute for Occupational Safety & Health to review the chemical weighing and mill ventilation projects. A full-scale working model of an 84" mill has been constructed in Cincinnati and NIOSH is ready to begin their ventilation experiments. This project has good potential to reduce air exhaust requirements and optimize hood design for more effective control of rubber processing fumes. At management's request, NIOSH factory trials will be postponed until after contract negotiations - earliest date late July/August.

19. Mr. Katzenmeyer visited the Tuscaloosa plant to conduct a radiation survey around a new X-ray backscatter gauge recently installed at the 4-roll calender. Shielding and interlocks were found satisfactory. The plant can put this unit in production.

20. NIOSH has begun their field studies to quantify butadiene exposures in monomer plants. Polymer plant selection should begin with approximately 50/50 chance of the Port Neches plant being selected for study. A more likely candidate in BFG would be the Akron plant because of multi products, some of which are unique to BFG. No final decision has been made for studies of butadiene polymer users. NIOSH is looking for information on residual butadiene levels in polymer. Additional work is needed to determine performance characteristics of butadiene air sampling methods in tire plants. At a recent RMA meeting, Mr. Katzenmeyer learned of sampling results by an insurance company in a competitor's plant which found butadiene 1-11 ppm in the tread department. Whether or not this is truly butadiene needs to be resolved.

21. The tire group approved additional ventilation in the tread department at Fort Wayne. We were told that our position statements in support of this project and the fact that it was an item recognized in previous ventilation task force visits dating back to 1976, were important in getting this project approved.

22. All death certificates and disability claims have been coded, formatted and entered into the system for the month. Race codes have been corrected where needed. It is anticipated that morbidity/mortality analyses will be run in mid-March.

23. Audio and pulmonary histories are being requested by the Louisville dispensary on a regular basis, department by department.

24. Assistance was provided to Ms. Pam Cordts at the Salisbury, North Carolina plant in the use of audio action reports. She will be handling the hearing conservation program for both Salisbury and Greenville plants.

25. Exposure reports for Louisville evidenced a problem with employee department and job assignments. The problem seems to have been identified in the system and correct reports should be generated after the March 12 population base update.

26. Mrs. Wallace entered 6,955 records into the system this month with an additional 13,645 records entered on Deer Park and LaPorte (1980-84) via the Pelam tapes.

H. W. Dietz

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