

February 5, 1985

R. A. Guyton, M.D.

Re: Environmental Health/Industrial Hygiene/Toxicology Activity Report
January 1985

1. Studies of the respiratory effects of 15 minute exposure to HCl in primates are continuing at Southwest Research Institute. Three month post exposure pulmonary function evaluation of one of the three baboons exposed to 5000 ppm HCl is now complete. Although none of the animals showed any effects at three days post exposure, evidence of changes in FRC and alveolar diffusion were evident in this one animal at three months. Confirmation of this observation will be complete by mid-February.

Because of scheduling needs, we began exposure of one baboon to 10,000 ppm (11,500 ppm actual). This animal tolerated this level well during the exposure, but showed clear pulmonary function and x-ray changes at day three post exposure. No further exposures at this level are planned. Pending the three month results from the 5,000 ppm animals, it is likely we will proceed to 500 ppm.

During Dr. Hinderer's visit to SWRI this month he also discussed the start-up plans for pulmonary function studies with rats and mice, the design of the primate lung, pathology work and future plans to develop a combustion system that will allow continuous generation of HCl from PVC.

2. Dr. Frank Cleveland (Cincinnati coroner) informs us that Dr. Jachimczyk (Houston medical examiner) is now back at work and is willing to discuss ways of setting the record straight regarding the Westchase Hilton fire. We are hopeful he will agree to a publication to counteract the Birky/Foundation for Fire Safety report. Dr. Hinderer will try to meet with Dr. Jachimczyk during his next visit to SWRI.
3. Final preparations are being made for initiation of dominant lethal and reproductive studies with Curerite 18. Dietary administration is expected to begin before the end of February.
4. The irritation and sensitization potential of several Hycar, Geon and Goodrite latex films has been evaluated. Two Geon products (576 and 577) were found to produce pronounced skin sensitization in a panel of human volunteers. The product group has been informed and is now checking the quality of the sample provided and preparing for possible changes in product literature. We do not believe this information requires a TOSCA 8(e) "substantial risk" submission since this is a reported potential hazard of one of the ingredients.
5. The results of further dermal toxicity studies with Goodrite XNP-5 continue to show a distinct sex difference. At 2000 mg/kg, no mortality has been observed in 15 male rabbits, while death has resulted in 7 out of 15 females. A full dermal LD₅₀ determination for the females has now been requested. This work will be used to support our FIFRA biocide registration.

We are hopeful that the final LD₅₀ value will be greater than 2000 mg/kg. Such a finding would enable us to use much less onerous wording on the label.

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6. Toxicology studies of Biofilm are now in progress. While some of the early reports are quite favorable, some cytotoxicity (in vitro) has been noted. This corresponds to reports from one potential customer that they are observing interference with wound healing. Efforts are now underway to determine what in the leachable fraction is causing this response.
7. Combustion toxicity tests with Estane X4100 white 123 appear to indicate greatly improved performance. Further studies are being conducted to verify these results.
8. The Chemical Group is interested in obtaining EPA clearance to manufacture two new water treatment chemicals (Goodrite KXP-65 and KXP-70). Toxicological testing is now in progress and it appears that we should be able to make our March 15 goal for submission.
9. Toxicological evaluations are in progress on Goodrite 3126 and studies on Goodrite 3150 are ready to begin as soon as samples are available. These studies are being conducted to meet labeling and customer needs and to support our TOSCA PMN submission. EPA has recently informed us that they will not grant us a PMN exemption for Goodrite 3150.
10. Irritation and sensitization studies have been completed on Carbopols 910 and 1342. No evidence of irritation or sensitization was seen in human patch tests with these materials.
11. We have been assisting the legal department in answering interrogatories for a number of lawsuits.
12. Dr. Hinderer attended a CMA meeting to prepare comments on the proposed OSHA Cancer Criteria. Comments have been submitted to OSHA.
13. Drs. Johnson and Hinderer attended a meeting with Chemical Group staff to discuss EDC ground water contamination at Calvert City. The Chemical Group is considering ways of dealing with this problem and requested our input on acceptable levels.
14. We have had no further word from the FDA regarding our petition to amend 21 CFR 178.1010 to permit various acrylic copolymers as components of food contact articles. The last 90-day review period expires March 28, 1985.
15. We were notified by the FDA on January 17 that the review of our petition to amend 21 CFR 178.2010 to permit new uses of 3114 in various olefin copolymers has been extended for 90 days. The second review period will expire April 15, 1985.

This petition is for use at a level not to exceed 0.1% by weight in the copolymer. At the time of filing it was thought the 0.1% level would be acceptable for all uses; however new uses have since been identified for a use level at 0.25% by weight. Mr. Bachtel advised the product group to await clearance at the 0.1% level before approaching the FDA for the higher level. Otherwise, clearance may be unduly delayed. Meanwhile, further extraction work can be undertaken for the increased loading level.

16. Extraction studies for us to petition the FDA for broader clearance of Goodrite 3125 in olefin polymers have been completed. The extractions are unusual in that the concentration of Goodrite 3125 in the 50% ethanol extraction solvent peaks at approximately two hours, then decreases to a substantially lower level for

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the next 238 hours. Apparently, after extraction the crystalline form changes to one less soluble which precipitates out of solution. Because of these unusual results, Mr. Bachtel scheduled a pre-petition meeting with the FDA on February 13.

At the request of R.T. Vanderbilt, Mr. Bachtel submitted the necessary forms to the National Sanitation Foundation to obtain clearance for the use of Goodrite 3125 in potable water applications.

17. The annual Drug Establishment Registration has been submitted to the FDA for the Calvert City Carbopol plant. The Cosmetic, Toiletry and Fragrance Association (CTFA) will include the Carbopol crosslinkers in the Carbomer monographs in the CTFA Dictionary of Cosmetic Ingredients. However, they will not include the polymerization solvent as we had requested. The inclusion of the crosslinkers should resolve the FDA's objection to the monographs for cosmetic labeling purposes. We asked the CTFA for generic names (Carbomer) for two new Carbopols (907 and 1342) which have found uses in cosmetics. We will also request generic drug names for these materials from USAN.

We completed analysis of some carbopol resins for residual benzene using the gas chromatographic technique sent to us by USP-NF. The values for residual benzene by this method are comparable to the current UV method. We plan to meet shortly with USP-NF to settle the benzene analysis question and to request a change in the NF monograph to include the crosslinkers in the definition of Carbomers.

18. A report on the extraction of some polyether Estanes has been received from IIT Research Institute. The report will be reviewed with the Estane Group to determine further work necessary in order to petition the FDA for the use of these materials in repeated use food contact articles.

Southern Research is filing an NDA for the use of Estane 5714 in disposable uterine diaphragms incorporating a spermicide. Mr. Dunn of S.R. indicated that our submission of the extraction report on methylene dianiline seemed to quiet some of the fears of the FDA for this use.

19. We submitted 13 additional Goodrite K-700 series resins to the USDA for acceptance in egg wash, steam line or primary cooling water systems and boiler water treatment formulations.
20. We just learned that the City of Phoenix is suing BFGoodrich over the Val Vista reservoir lining. The city refuses to use the reservoir and has placed bids for its removal and replacement. The apparent low bidder proposes to use most of the existing BFGoodrich liner, but with a different sealing system.
21. Dr. Johnson met on several occasions with the attorneys in the Kemper suit to assist in responding to interrogatories and request for documents.
22. NSF is insisting that the orange dye used in CPVC sprinkler system pipe be subjected to 90-day feeding studies and an Ames test. We have begun Ames testing and will be finished in a few days. Preliminary indications are that this test may be positive. If so, we will assist the Chemical Group in any way we can in the inevitable negotiations with NSF that will ensue.

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23. Multiple problems persist in the programming of the medical surveillance system. So much time and expense is being devoted to correcting problems in reports that had been standard and routine for several years until December 1984 and we are competing with so many other demands that we have been unable to keep the system current. We are unable to efficiently comply with the hearing conservation law for example. Other examples include the cotton dust monitoring report and the audiometric action reports required by OSHA, and the medical scheduling program, all of which require extra effort and repeated screening.
24. Major effort was devoted to the decentralization of industrial hygiene. Mr. Bialke has been transferred to the Chemical Group. Negotiations continue with the business groups formerly known as EPG over timing and individual. Tire Group will accept an individual for their engineering group.
25. Required information has been received from the Louisville plant personnel office after a three month delay so that we may now proceed to complete their job identification program.
26. Mrs. Wallace entered in excess of 8,500 records into the system.


H. W. Dietz

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