

H.W. Dietz

August 14, 1986

J. D. Ong

Activities Report - July 1986
Health & Environmental Services Division

Environmental Health

1. The Kentucky EPA notified BFG that it was preparing to issue a drinking water alert because of ethylene dichloride contamination in groundwater and river at Calvert City. At Geon's request, R. K. Hinderer attended a meeting with the EPA where presentation of technical and practical reasons why such action was not necessary induced the Agency to postpone an alert, pending further evaluation.
2. The two year effort to obtain clearance for use of an orange dye in CPVC pipe for sprinkler systems has finally been successful. The CPVC group sent a letter of appreciation for our assistance.
3. R. K. Hinderer attended a meeting of the CMA Rubber Additives Panel. In preparation for required testing under TOSCA, Section 4 rulemaking, we have begun studies on the pharmacokinetics and metabolism of MBTS and MBT. Initial results have indicated that both are handled similarly and have suggested that there may be a technical basis to support testing of one, rather than both chemicals. During the meeting, "Mr." Hinderer provided comments and recommended changes in the draft report. He also provided an update of the results of mutagenicity studies on MBTS that we have conducted at Brecksville.
4. Dr. H. W. Dietz continued to review workers' claims for hearing loss and pulmonary function loss to assist the Miami plant in determining which cases to attempt to settle and which to deny. Many of those denied may return again as claims through an attorney.
5. The material safety data sheet file continues to grow and is reasonably complete in relation to the information supplied by the various plants. Many plants have not supplied lists of

BFG28380

23864001

Activities Report - July 1986
Health & Environmental Services Division - contd

Environmental Health - contd

5. Contd

materials; others have supplied lists showing they are not in compliance with the Hazard Communication Standard (record of no MSDA on file), while a minority have submitted complete, intelligible lists, and are now in compliance as regards files of MSDS's. Sets of MSDS's with indices have been supplied to Tuscaloosa, Akron Chemical, Akron Aircraft Tire, Tire Headquarters, Livonia, Ft. Wayne, Plaquemine and two sets to Chemical Group.



Richard A. Guyton

cc: P. C. Ross
L. Carter
R. A. Eisentrout
L. V. Triggiani

23864002

BFG28381

August 5, 1986

R. A. Guyton, M.D.

Activities Report - July 1986
Environmental Health/Industrial Hygiene/Toxicology

1. We have begun the third and final phase of the VI primate and rodent studies of HCl and PVC. In our earlier studies we found that baboons (unlike mice and guinea pigs) could survive fifteen-minute exposures to levels as high as 10,000 ppm and that only at this level was there any suggestion of pulmonary function effect following one year post-exposure observation. This month we exposed the first baboon to PVC decomposition products containing ~5,000 ppm produced under nonflaming conditions. The initial observations indicated that the primate response to 5,000 ppm HCl (pure gas) and 5,000 ppm HCl generated during nonflaming combustion of PVC are similar.

These data continue to support the conclusion that HCl is less toxic than many have alleged. This final phase will enable us to determine whether (as some have alleged) PVC smoke (particulate) carries the HCl deep into the lung, therefore increasing the toxic effect. While we still have much to do in order to answer this question, including the testing of worst case conditions (flaming), the first PVC exposure is certainly encouraging.

2. Earlier this month the Kentucky EPA notified BFG that it was prepared to issue a drinking water alert because of EDC contamination resulting in ground water and river contamination from our Calvert City plant. At the request of the Geon Division, Dr. Hinderer attended a meeting with the EPA. We presented a number of technical and practical reasons why this was not necessary and were able to get them to hold off on the alert pending further evaluations.
3. Mr. Bachtel attended the NSF Drinking Water, Health Effects Task Group meeting July 8, 9. The mission of this group has been defined so as to develop an accurate, precise, expeditious procedure to evaluate the safety of direct and indirect water additives. Much discussion centered on confidentiality, use of data and "threshold of regulation" concepts. It was apparent that NSF has an ultraconservative approach. Much work needs to be done. It seems that this will be a long, laborious process. We have, as requested, written a proposed evaluation procedure to be submitted for review by the task group.

23865001

BFG28382

4. The Cosmetic, Toiletry and Fragrance Association (CTFA) has officially adopted the generic name Carbomer 1342 for Carbopol 1342. Because Carbopol 1342 is an acrylic copolymer rather than a homopolymer, polyacrylic acid, there had been hesitancy on the part of CTFA to assign the same generic name (Carbomer) as has been assigned to the other Carbopols.

Abbott Labs is interested in using Carbopol 934P in an oral pediatric pharmaceutical. They had requested copies of all toxicity studies done on C-934P. Instead, we have set up a meeting with Abbott representatives to discuss the toxicity studies and other data. From the detailed list of questions submitted prior to the meeting, it is apparent that the present toxicity data on C-934P will not satisfy Abbott's needs.

To resolve several questions, Mr. Bachtel has discussed the regulatory requirements for toll manufacture of polycarbophil, U.S.P. with the FDA. According to the FDA, the toll manufacturer must be registered as a drug establishment, be solely responsible for good manufacturing practice, and meet USP monograph requirements. Labeling requirements were also determined. BFG's warehouse need not be registered so long as it is only a warehouse.

5. The Fabricated Polymers Group wants to obtain NSF listing for KoroKlear hanging door strips under NSF Std. 51. These hanging door strips are used for "walk in" freezers and refrigerators. We cancelled our Std. 51 listing for rigid Geon compounds at the beginning of the year. In order to list the hanging door strips in the quickest time possible, it was necessary to reinstate the listing for the Geon 87300 compounds and then add the door strips. We will later cancel the Geon listings.
6. A competitor claims to have FDA acceptance for his polyurethane for use as bottle cap liners. Mr. Bachtel received a letter from him citing his FDA clearance. The regulations he cited are the same ones the Estanes are cleared under. These do not permit polyurethanes to be used as bottle cap liners. Mr. Bachtel has written to FDA for an opinion on the use of such resins in the above application.
7. The SP&C Division has asked us to review the hazard statements on the U.S. and European labels for Cure-rite® 18 and to translate the highly technical results of our toxicology evaluations into a form which is easily understandable. Dr. Hinderer has prepared a draft summary of these results and has distributed this for review. Recommendations for harmonizing U.S. and European label requirements will be made shortly.

BFG28383

23865002

8. At the request of Dr. O'Mara, Dr. Hinderer reviewed and prepared a summary of toxicological evaluation of the Joint Expert Committee on Food Additives of the Food and Agricultural Organization and the World Health Organization for VCM and DEHP. He also recommends that we oppose "Provisional acceptance" based on the concept of "lowest levels technicologically achievable".
9. We have finally obtained clearance for the use of an orange dye in CPVC pipe for sprinkler systems.. We received a letter of appreciation from the CPVC group for our assistance in this two-year effort.
10. Dr. Hinderer attended a meeting of the CMA Rubber Additives Panel. In preparation for required testing under TOSCA Section 4 rulemaking, we have begun studies on the pharmacokinetics and metabolism of MBTS and MBT. Initial results have indicated that both are handled similarly and have suggested that there may be a technical basis to support testing of one rather than both chemicals. During the meeting Dr. Hinderer provided comments and recommended changes in the draft report. Furthermore, he provided an update of the results of mutagenicity studies on MBTS that we have conducted at Brecksville.
11. Efforts to obtain pesticide registration for Promac products are continuing. The toxicology data, worst case exposure scenarios, and data waiver requests are ready for submittal. We expect that the complete registration package will be submitted in the next few days once physical/chemical evaluations are complete.
12. The CMA has asked our assistance in preparing a representative who will attend two upcoming meetings of the International Agency for Research on Cancer (IARC). These meetings are important since the IARC cancer classifications, according to the OSHA Hazard Communications Rule, must be used to determine whether a label must contain a cancer warning. We have volunteered our services for certain chemicals and have asked to be kept informed with others.
13. We received a verbal report of an allegation of an adverse health effect involving Geon 137. We have asked the Geon Division to comply with Company policy by completing a BFG "TOSCA 8c" reporting form. We emphasized that the importance of this goes far beyond regulatory compliance. The policy provides BFG health professionals with a tool for gathering information to identify and facilitate the mitigation of potential health hazards associated with our products or operations.

BFG28384

23865003

14. Uniroyal/Goodrich representatives have asked for estimates of costs to provide certain services to Akron. These chiefly involve information services using The Medical Surveillance System and BASIS. Whether this will lead to any business for D/0020 is unknown.
15. Dr. Dietz continued to review workers' claims for hearing loss and pulmonary function loss to assist the Miami plant in determining which cases to attempt to settle and which to deny. Many of those denied may come again as claims through an attorney.
16. The material safety data sheet file continues to grow and is reasonably complete in relation to the information supplied by the various plants. Many plants have not supplied lists of materials; others have supplied lists showing they are not in compliance with the Hazard Communication Standard (record of no MSDS on file) while a minority have submitted complete, intelligible lists and are now in compliance as regards files of MSDS's. Sets of MSDS's with indices have been supplied to Tuscaloosa, Akron Chemical, Akron Aircraft Tire, Tire Headquarters, Livonia, Ft. Wayne, Plaquemine and two sets to Chemical Group.
17. Dr. Dietz attended a deposition of Marvin Legator for the Geon Vinyl Company in a suit involving a plant closure by Celanese.
18. Sherrill Snedeker who was the in-house "BASIS Expert" was one of the casualties of the Uniroyal-BFGoodrich merger. It appears that Suzanne Marcy, Information Specialist and DBA at Brecksville, will assume some/all of Sherrill's BASIS responsibilities for the technical libraries--nothing official as yet. We also understand that Jim Lowe, Tire MIS software support person and the only MIS support person who knows BASIS, will continue his BASIS support for an additional six months. Hopefully, this allows him enough time to "successfully" do a walk-through of BASIS with his replacement, Emmet Gallagher.
19. The population of the EREF database continues and currently contains 1778 records. Ms. Dillon has responded to numerous search requests for EREF data for R. K. Hinderer.


Harold W. Dietz

jp

BFG28385

23865004