

January 6, 1987

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Activities Report - December, 1986
Environmental Health/Industrial Hygiene/Toxicology

1. The Medical Surveillance System has been converted entirely to direct data entry. Key punching is eliminated and all data and requests for reports are entered through the terminal. Unfortunately, the terminal then developed problems. Combined with the learning phase, this terminal problem leaves us somewhat behind in data entry. Maintenance has been less than satisfactory. Despite this, medical exam scheduling was provided to four Uniroyal Goodrich and four Goodrich locations.
2. The reports of this year's examinations of members of URW Local 5 by Health Examinetics are being received. In December 243 reports were received and reviewed. Of these, 18 are reported to have chest X-ray changes which could be related to asbestos exposure; 11 with pleural thickening or plural plaques, six with pneumoconiosis with features seen in asbestosis and one described as possible pneumoconiosis without any features characteristic of asbestosis.
3. The HYTOX (MSDS source) database continues to grow. It now contains approximately 1300 records. More locations are becoming active in assisting with revisions and updates indicating greater awareness and use of the system. We plan to provide all facilities with updates to their respective MSDS collections during January. Mr. Katzenmeyer, UGT and Amba Sargent, Plant Protection, have been supplied complete sets.
4. Mr. Modrell has nearly completed the MSDS file for BFG Graphic Arts as well as updating and preparing sheets for Marietta, Akron Chemical, Louisville, Pedricktown, Avon Lake and Marietta. He also reviewed the status of facility lists for IPD and A&DD locations and initiated a program to obtain better lists.
5. The FPD notified us that they have received conditional pesticide registration for several ProMac formulations and expressed their appreciation for our assistance. Dr. Hinderer is continuing to assist the Division in providing EPA with the required additional information and in determining registration requirements in other countries.

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6. The Calvert City Carbopol facility was inspected by the FDA on December 11, 1986. The inspector found the plant to be totally in compliance with Good Manufacturing Practice (GMP) guidelines. However, he questioned our practice of reprocessing off-spec material. He suggested this "gray" area should be reviewed to verify compliance with GMP. Because Carbopol is a bulk drug ingredient of a specific chemical identity (i.e., not a finished pharmaceutical in dosage form) such reprocessing is acceptable so long as the end product meets all NF specifications.
7. Plans are moving forward to manufacture and market calcium polycarboxylate, USP (Carbopol EX83). The product will be toll manufactured for BFG by Dan River, Inc. In preparation for this activity, forms for FDA-GMP compliance have been reviewed and accepted. Also, in compliance with the Drug Listing Act, the necessary FDA forms for Drug Product Listing are being completed for submission to the FDA.

One problem has occurred. Divinyl glycol (the crosslinker) cannot be found on the TSCA inventory. We have asked our supplier to verify its TSCA status before we can go further.

8. At the December meeting of the VI Technical Committee, Dr. Hinderer provided a progress report on the primate/rodent toxicity studies of HCl gas and PVC decomposition products. All studies with HCl and primate exposures to PVC decomposition products have been completed. One manuscript on the toxicity of HCl in primates has been prepared and a second one on its comparative response in rodents and in primates is in progress. These studies continue to indicate that PVC is not unusually toxic and that many allegations about PVC and HCl are false.
9. In accordance with TOSCA 8d requirements we have provided copies of health and safety data on acetonitrile, antimony, asbestos, methylene chloride, methyl ethyl ketone, toluene, trichloroethane, methyl isobutyl ketone, xylene organotin compounds and cyclohexane. Another Federal Register notice is also being reviewed to see if further reporting is needed for other chemicals.
10. Arrangements were made for toxicological evaluations of a PVC compound from our Venezuelan subsidiary. This compound is intended to be used in medical device applications. Initial biocompatibility studies were favorable.

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11. Dr. Hinderer has assisted the IISRP in preparing and submitting comments this month to OSHA regarding their Advanced Notice of Proposed Rulemaking for butadiene. The Institute recommended a workplace standard of 10 ppm based on the greater sensitivity of rodents to BD compared to man. It was also noted that the cost of meeting 10 ppm could be as high as \$5,000,000 for some plants. Although a 10 ppm level could be achieved through existing technology, IISRP stated that the feasibility and associated costs of meeting a ppm standard are unknown.
12. On December 2-3 Mr. Bachtel attended the SPI FDCPMC semiannual meeting. Various current FDA regulatory activities including the SPI Threshold of Regulation petition and the FDA PVC proposal were discussed. Current activities of the EPA and OSHA impacting the FD&C packaging interests were also discussed.

Current activity on the FDA PVC proposal has been caught up in a quagmire of comments concerning the environmental impact of the proposal. Numerous comments from consumers, and environmental groups questioning incineration and waste disposal must be resolved. SPI is submitting comments to counter the alleged unfavorable impact. Meanwhile, the BTAF will not approve PVC liquor bottles until FDA has issued a final PVC regulation. This appears to be a long way off.

13. Sparlets, a division of McKisson, is interested in the use of PVC bottles for potable water. In preliminary extractions vinyl chloride monomer (detection level 0.25 ppb) could be detected in the water contained in 1.75 liter PVC bottles. However, because of California Proposition 65, it is uncertain whether this level of detection is low enough to avoid the labeling provisions contained in the law.

Mr. Bachtel has discussed this situation with representatives of the California Department of Health. Some of them seem to be as confused as everyone else about the ramifications of Proposition 65. One person in the bottled water program felt that if the container complied with U.S. FDA requirements, it would be acceptable. Some mineral waters are being imported in PVC bottles presently.

We are planning an extraction study on a number of bottles to simulate a 6-month shelf life. If no VCM can be

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detected in these at a level of less than 0.25 ppb we should be able to assure their compliance with Proposition 65. The current California recommended MCL for vinyl chloride in potable water is 2 ppb.

This could be a significant market for rigid Geon compounds.

14. At the request of the SP&C Division, Dr. Hinderer testified at a hearing in Madison, Wisconsin regarding additional clearances for the use of CPVC pipe. As the result of a joint effort of a number of people, we were successful in obtaining the desired plumbing code change.
15. The reformulated KoroKlear Vinyl Strip and Sheet compound has received a favorable review by the National Sanitation Foundation (NSF). NSF has requested compound samples for qualification extraction testing. Apparently Mr. Bachtel's last letter to the NSF contact with a copy to their CEO and Vice President has gotten some positive results.

The minor reformulation of KoroKlear to overcome NSF's objections has necessitated resubmittal of the formulation to USDA for their acceptance.

16. Mr. Modrell consulted with John Epperly, Marietta Plant, on a problem of solvent vapor contamination of packaging material in a leased warehouse. Mr. Epperly was referred to Mr. Driscoll to discuss the need for legal counsel.
17. Mr. Modrell discussed asbestos test methods with Mr. Bialke and provided a copy of the EPA method for determination of asbestos in bulk insulation samples.
18. Ms. Butterfield provided assistance to Mr. Brinkley in accomplishing job surveys of the Akron Complex and to Mr. Franklin in the management of cotton dust survey data at Martha Mills.
19. Ms. Dillon made a presentation on HYTOX to the Brecksville Corporate Research group. Approximately 50 attendees showed an interest in the system and many may find it useful.

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20. Earlier this year we noted that some investigators at NYU reported that acrylic acid was carcinogenic. Because this report was in conflict with earlier studies and because the EPA has increased its concern and regulation of acrylates, the Institute for Polyacrylate Absorbants initiated a large program to address these issues.

Since BFG receives only limited information through its affiliate membership, Dr. Hinderer attended the Annual Institute meeting. We received considerable information on the chronic and subchronic studies of acrylic acid polymer and monomer. Several presentations also discussed regulatory activities and various health issues that have been raised.

21. The SP&C Division asked us to assist a customer who is seeking EPA potable water clearance for a product that uses Estane® 5750. Information in support of their potable water application was sent.
22. Dr. Dietz attended the continuation of the deposition of Dr. Marvin Legator, a plaintiff's expert in a suit against Celanese, BFG and others alleging various adverse health effects in former Celanese employees due to exposure to PVC (and residual VCM).
23. Our support of two new catalysts for reaction injection molding continues. Protocols have been finalized and some testing has begun. These toxicological evaluations should be complete by the end of January with reports available in February. These studies will support TOSCA/PMN for these materials.
24. Dr. Hinderer attended a joint meeting of the CMA Panel on BD and the IISRP. The group discussed individual activities directed toward affecting OSHA standard setting for BD. An effort was made to coordinate health related activities of BD producers and users. Political and legal options were discussed.
25. The annual EPA Pesticide Report forms for No Foul Rubber and ProMac have been received. These have been forwarded to the appropriate BFG persons for completion.

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26. The formulation of Estane 58277 has been submitted to the EPA, Office of Drinking Water as requested by Deerfield Polyurethanes Co. Deerfield has a potable water application for Estane 58277 film.

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