

June 5, 1987

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Activities Report - May, 1987
Environmental Health/Industrial Hygiene/Toxicology

1. Input into the HYTOX (MSDS) database continues. In addition to input on new chemicals, we are attempting to edit and revise existing records to improve data, correct errors and add company identifiers. As part of this we are printing more often so that the office copies are more current.
2. Mr. Modrell reviewed the status of A&DD plants and the Medical Surveillance System with Dick Driscoll. A&DD appears to be interested in continuing the MSS services.
3. We reviewed asbestos labelling requirements for the Bloomington Plant at the request of Kevin Ryan. It was recommended that cartons of asbestos brake linings be labelled in accordance with the OSHA asbestos standard.
4. Following correspondence and a telephone consultation with Randy Emmelhainz at IDI/Battelle, Ms. Dillon attempted to add the "Disclaimer of Liability" statement to the MSDS Driver file with the assistance of Emmett Gallagher, Data Center Support. One of the enhancements needed to accomplish the task was changing the file format to support an 820 character record length, and TSO/ISPF would not allow her to edit the file with that large a record length. So we are back to the drawing board, and she will try the next alternative.

If worse comes to worse, Emmett Gallagher can write a program to support the enhancement.

5. Coding and entry of death certificates has been caught up and is now current. We have received no death certificates on Tire Group employees since April; we are interested in former BFG employees transferred to UGT including those retirees who were never in Tire.
6. We have received tapes from Aetna Claims Department and processed their ICD codes into our files. Errors from Oct., 1986 to the present require correction. Since Aetna "zero-fills," many correct codes are being rejected. Iris Para is discussing their changing to "correct code only" with Aetna along with other programming difficulties. Another problems is that Aetna has been coding only hospitalization and surgical cases.

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7. On May 8, 1987 Mr. Bachtel visited the Louisville PVC compounding area to perform a Good Manufacturing Practices (GMP) audit for "FDA" type PVC compounds. Louisville has excellent experience producing bottle cap liner (beer, Coke, etc.) for Alcoa but does not exercise the same care for other "FDA" products. Several recommendations regarding product traceability, raw materials, sample and records retention, and warehousing have been made to insure compliance with GMP.
8. The UGT management was proposing to use BHT in place of Geltrol as an antioxidant in SBR production at Port Neches. Concern was expressed about the FDA clearance of Geltrol. Mr. Bachtel participated in a phone conference with A. Bettick, Ray Taylor and Port Neches and satisfied Port Neches' questions about Geltrol. It appears SP&C will retain this business.
9. Dan River is concerned about employee exposure to polycarbophil dust. Dan River is toll manufacturing polycarbophil for BFG. No information is available concerning inhalation toxicity of polycarbophil. Because it is a cross-linked acrylic acid polymer similar to the Carbopol resins, Mr. Bachtel reviewed the 1982 National Starch TSCA 8(e) submission and medical review of BFG Calvert City Carbopol employees. Based on this review we would not expect adverse pulmonary effects from exposure to calcium polycarbophil when controlled in accordance with the ACGIH TLV for nuisance dust.
10. Dr. Hinderer has completed the final draft of the IISRP response to OSHA on the ICF-Clement risk assessment for butadiene. These comments have noted many serious problems including numerous omissions of data, lack of critical review, unfair and unfounded criticisms of some data, and the use of inappropriate models for risk assessment. This document has been submitted to IISRP for review by the international member companies.

Dr. Hinderer met again with Multinational Business Services' staff on butadiene. MBS provided an update on OSHA and EPA activities. Specific actions planned by MBS were discussed and support tasks were assigned to various IISRP member company representatives. He also notified Gerrie Bjornson of our Washington office about this activity.

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11. The Technical Committee met during the annual meeting of the VI. The committee discussed a number of health issues regarding the manufacture, use and disposal/incineration of PVC. Dr. Hinderer provided an update on the primate/rodent studies with HCl and PVC combustion gases and noted that the first manuscript of this work had been accepted for publication. The group felt this information was very important and discussed future communication needs.

As a result of this basic research on the appropriateness of rodents as models of HCl and PVC combustion gas toxicity in primates (i.e. man), Dr. Hinderer received an award in recognition of outstanding service and contributions. This award was particularly appreciated since he developed the program, got the necessary approvals, was a major participant, and has been included as an author of some very important research.

12. We have responded to the Cosmetic, Fragrance and Toiletry Association's (CFTA) request for updated product and acrylic type polymers information. We have updated the lists of BFG acrylic acrylate copolymers (Carbosets), polyacrylic acid (Good-rite) and carbomer (Carbopol) products for inclusion in the 4th edition of the CTFA Dictionary of Cosmetic Ingredients.

We also proposed new definitions for some of the polymers. In addition, we proposed and provided rationale for a family monograph for the Carbomers rather than individual monographs for each numbered resin. This would permit more flexible labeling for cosmetic manufacturers and inclusion of new BFG products.

13. We were contacted by a former employee concerned about his possible benzene exposure while working at the Akron Plant. Job Exposure reports from the system indicated that benzene was present on his job only as a component of the rubber solvent mixture used. Dr. Dietz discussed this information with the gentleman and an MSDS for Rubber Solvent was sent to him.
14. A question concerning a possible rise in suicide among former employees during the last four years was posed by the Human Resources Department. Mortality and Morbidity reports for the time period failed to show a problem.

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15. A number of MSDS sheets were prepared and entered into HYTOX in response to special requests from various business units. These were chiefly in response to requirements by customers for MSDS's before purchase of products. Mr. Modrell has been able to meet the time requirements on all of these. Also, there were several requests for printouts of existing MSDS files. All these requests were filled by Ms. Dillon and Mr. Modrell.
16. A report was created by Ms. Percy for K. Stimler listing requested items from the database with specific fields included to assist in dealing with problems raised by California Proposition 65.
17. Last year we received numerous boxes of tissues from previous toxicology studies for permanent storage within BFG. A secured area has been established at the Brecksville warehouse and these have been transferred there.

Periodically the wet tissues must be checked for leakage of the formalin preservative. Ray Taylor and Dr. Hinderer checked a few of these boxes and repackaged a number of tissue specimens from the dominant lethal and reproductive studies on CR-18. They will need to check approximately 100 boxes sometime this summer.

18. Based on the cost and time estimates we obtained, the SP&C Division has decided to conduct toxicology evaluation to support the use of Carbopol made with ethyl acetate as a carrier for a new pediatric pharmaceutical. We have requested draft protocols for absorption and 30-day feeding studies in rats. 90-day and 6-month studies in rats and dogs will be needed in the future.
19. At the request of the Geon Division Dr. Hinderer provided a critical review of the NBS study "Fire Toxicity Scaling." This report dealt with an evaluation of the NBS N-gas model for predicting fire toxicity from materials. The model appeared to correlate well with large scale test but not the small scale NBS combustion toxicity test.
20. Twenty-one documents derived from work done on BioFilm 102 were submitted to the National Center for Devices and Radiological Health for inclusion in Device Master File MAF #54. These documents will be used to support a Premanufacturing Authorization (PMA) for BioFilm. Sales are anticipated in the second half of 1987.

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21. One of our customers, Premier Chemicals, has an application for Carboset 514 in freeze protection and fertilization control for agricultural products. Mr. Bachtel reviewed this application with the EPA. So long as no pesticidal claims are made, this application falls outside of FIFRA and no registration or contact with the agency is required. This information has been relayed to the customer.
22. Mr. Bachtel met with representatives of Dow and DuPont on May 19, 1987 to plan our strategy for the pre-petition meeting with FDA for the next day. Dow, DuPont and BFG plan to petition to amend 21CFR 177.2600 "Rubber Articles for Repeated Use" to include polyether urethanes.

Joint submission of a petition by competitors and raw material suppliers is unusual for FDA. However, they did not foresee any problems in handling such a petition. As anticipated, FDA did not accept our minimal proposal; however, the amount of data requested was less than normally required in the past. BFG, Dow and DuPont will share the work required. BFG and Dow will write the final petition, submitting separate sections on the manufacturing process and environmental assessment as appendices to the main petition. Since these sections may contain confidential business information, it will be necessary to submit them separately. A tentative timetable has been developed calling for submission of the final petition in January of 1988.

23. The pace of TSCA Section 4 test rule development within EPA has slowed somewhat over the last six months. This has resulted in a beneficial delay of the finalization of the test rule on MBT and the promulgation of those for the other rubber chemicals. On the negative side NTP has reported that MBT is carcinogenic in rats. These results are expected to have an adverse effect on other MBT-based chemicals such as MBTS which is metabolized to MBT.

The CMA Rubber Additives Panel met this month to discuss these new developments and to plan for future activities. Because of the similarities between MBT and MBTS the group discussed the possibilities of conducting a cancer bioassay with MBTS. The panel members felt that this would also help answer unresolved issues regarding the MBT cancer bioassay.

Another highlight of the meeting was the efforts of the Panel to get importers to share in the testing costs.

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Under TSCA EPA can require importers and users to share in the costs of mandated testing. CMA distributed a draft letter to pay now and have some input or be on notice that we will ask later.

24. Toxicological evaluations of Norcat M, S, and AS have been completed. Toxicology summaries were prepared and were submitted along with the test reports for inclusion in the PMN on the products.
25. Ms. Dillon is presently working with Elmer Nowak, Chemical Group MIS, to provide us with access to the Chemical Company's Recipe File. The access process is currently being revised.
26. 144 reports were processed by Ms. Butterfield for the A&DD Workers' Compensation Department.
27. Employees at Avon Lake have expressed concern over a possible excess of bronchitis and pneumonia in the Polymer Chemicals Semi-works at Avon Lake. This was discussed in a meeting at Avon Lake on May 29 and actions to better define the problem and to reduce exposure to possible offending chemicals were agreed upon. Henry and Akron Chemical which have similar operations are to be advised.
28. Dr. Dietz participated in a UGTC safety managers' meeting on May 5 and 6. Topics of discussion included medical monitoring, MSDS and the Medical Surveillance System.
29. Ms. Butterfield spent three days training Phyllis Siebel at Uniroyal-Goodrich in data entry and report request for the Medical Surveillance System. We will continue to support their system through advice, coding and audio and pulmonary reviews.
30. USP Class VI - Biological Tests for Plastics were performed on three Geon experimental compounds. Only one of the three compounds passed the tests as run. In spite of recommendations to have the tests run at the lower standard extraction temperature (50°C), Avon Lake has had them performed at 121°C. This is a very severe test for PVC, way above normal use temperatures. This may likely be the reason for the failures.


Harold W. Dietz