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

1. The proposed USP-NF Carbomer monographs published in the Pharmacopeial Forum were discussed at the September Carbopol PMG meeting. After two years of repeated discussions and reviews, the full ramifications of complying with the Carbomer monographs, when official, has just been fully realized by the PMG group. The increased production costs associated with Good Manufacturing Practice (GMP) and monograph compliance (i.e. extensive records, testing, and FDA inspections) far outweigh any economic benefits derived from official monograph status. In addition there is some concern that the new non-benzene Carbopols may vary somewhat from the proposed monograph specifications. Therefore, at the request of the Carbopol PMG, Mr. Bachtel will attempt to have the proposed USP-NF monographs withdrawn.

   As a result of these discussions, concern was expressed as to how well the Calvert City Carbopol plant is complying with GMP's. At the request of D. Henneke, Mr. Bachtel will audit the Carbopol manufacturing facilities on October 8.

   Abbott Laboratories has postponed development of their oral pediatric pharmaceutical until non-benzene Carbopol 934-P is available. They are extremely sensitive about using any Carbopol polymerized in benzene regardless of the residual solvent level.

   They have, however, asked to have authorization given to the FDA to refer to Carbopol Drug Masterfile for a number of other uses for Carbopol 934-P.

2. Both Dr. Hinderer and Mr. Bachtel attended the second NSF water additives Health Effects Task Group meeting Sept. 23 and 24. Only two task group members (BFG and Dow) had submitted decision tree proposals for approving water additives for discussion. As the Dow representative was absent the first day, the BFG proposal was thoroughly discussed. It served as a model from which a draft of the toxicological data requirements was developed. The resultant draft was more liberal than the BFG proposal. It was generally accepted that the toxicological requirements should be tiered depending on possible exposure in "finished water at the top." It was also agreed that a risk of 10^{-6} would be used for potential carcinogens. In addition,

safety factors were proposed for the evaluation of risk from other toxicological findings.

This meeting represented an almost 180° turn around from the initial task group meeting. We were generally pleased with the direction taken and progress the group has made.

3. Dr. Hinderer and representatives from Shell and Insituform met with EPA staff to discuss some of the agency's concerns about our joint potable water application. One of the major areas of interest to EPA was the significant amount of materials leaching from the polyurethane (BFG) component. Although Dr. Hinderer recommended a program for toxicological evaluation of the Estane leachate about a year ago, no work was approved. As a result we are faced with the task of developing an abbreviated testing program. While it is possible that this limited data will ease some of EPA's concerns, it is clearly far from adequate to satisfy product stewardship needs.

4. In June Dr. Hinderer testified in Chicago before Mayor Washington's Ad Hoc Advisory Commission on the use of plastic pipe. As a result of that testimony Dr. Hinderer was asked by the Commission to testify before the City Council during the hearing on plastic pipe. His presentation addressed acute and chronic combustion toxicity concerns.

5. Problems continue with the shortage of industrial hygiene capabilities. This month Mr. Modrell instructed Ray Heffner (Adhesives) and Dick Roten and Eugene Koprives (D/4375) on asbestos monitoring techniques and loaned them equipment for this purpose. Also Vern Infantino (D/1641) was provided equipment and instructions to evaluate employee exposure to solvent vapor. These people are not skilled in the use of this equipment and there may be some doubt as to the validity of their data.

6. Mr. Modrell worked with representatives of the Elgin and Akron Chemical plants, D/0063, A&DD and IPD to clarify the preparation, use and interpretation of MSDS's and the requirements for plant inventory lists.

7. Bob Modrell and Mrs. Dillon met with Amba Sargent from Plant Protection and addressed the problem of timely responses to outside calls for pertinent data in an emergency situation. It was suggested that instead of Plant Protection recreating the wheel we invented, we could provide them with a current selection of our "MSDS Report" and their respective indices and any future quarterly supplements. It makes good sense that they have this data at their fingertips since they respond to emergency calls on a 24-hour basis. Consequently, we provided them with their first installment of 972 records plus indices.

8. Ms. Dillon assisted Dr. Hinderer in a thorough search of the KWIC Index for missing documents (hard copies) in conjunction with a search of his files for duplicate documents. As a result of this search, Ms. Dillon added and deleted numerous documents (records) in the EREF database. This concerted effort aids us in maintaining a state-of-the-art database which now contains about 2,000 records.

9. Amendment of 21CFR178.2010 "Antioxidants and/or Stabilizers for Polymers" to permit a new use of Goodrite 3125 in olefin copolymers was published in the Sept. 2, 1986 FEDERAL REGISTER. This expanded use of Goodrite 3125 was in response to the BFG petition, FAP4B3862, filed with the FDA July 9, 1985. Subsequent to filing this petition, Goodrite 3125 was sold to Ciba-Geigy. The FEDERAL REGISTER publication noted Ciba-Geigy's purchase of this antioxidant.

10. John Moriarty of Master Processing indicated to Mr. Bachtel that EPA had requested that Master Processing submit the confidential composition of No Foul and the supporting safety and efficacy data. Since the No Foul composition is confidential to BFG and since BFG owns the supporting data, Master Processing is not free to submit such information on their own.

    Mr. Bachtel discussed this situation with the EPA Pesticide registration office in Washington, D.C. and the California Regional EPA office. Apparently there was some misunderstanding. Master Processing, as a contractor for BFG, does not have to submit such information.

    Mr. Bachtel received a copy of Master Processing's EPA annual pesticide production report. Rather than just No Foul, Master Processing has listed four antifouling compositions. Two of these are solely for export to Japan and need not be listed. The other two are the No Foul rubber system and should be listed as one. Mr. Bachtel is providing guidance to J. Moriarty to correct these reports.

11. DuPont wants to use CPVC in a fruit juice concentration application. They have asked for any extraction studies which might be relevant.

    Mr. Bachtel reviewed two studies done on CPVC and PVC water pipe which may be suitable. He informed DuPont that the study done for the Vinyl Institute cannot be released until it has been made public. This will take about a month. DuPont is willing to wait.

12. This month EPA published a final rule under TOSCA Sect. 8d which expanded the scope of reportable health and safety data and extended the sunset provision for reporting to ten years. As a result of this rule we submitted information on cyclohexanone and are presently reviewing our files for information on other chemicals.

13. Dr. Hinderer observed the first primate exposure to PVC combustion products under flaming conditions. Although previous exposures of baboons to PVC under non-flaming conditions proceeded satisfactorily, this first exposure was important because we knew it would produce large amounts of particulate. Many have speculated that particulate absorbs HCl from the burning PVC making it more toxic by carrying it farther into the lung. While we will have to wait one year for completion of the post-exposure pulmonary function evaluations, initial observations failed to suggest deeper penetration. All primate exposures are expected to be completed shortly.

    A progress report of this research was provided at a recent meeting of the VI in New Jersey.

14. EPA has raised some concerns regarding our Promac pesticide registration petition. In an effort to clear this hurdle we have provided our consultants with some additional information and arguments to use in discussions with EPA.

15. Dr. Hinderer is continuing to assist in preparing a CMA representative for upcoming meetings of the International Agency for Research on Cancer (IARC). Literature on the short-term mutagenic evaluations of butadiene are being gathered and reviewed. No response on VCM is planned because such a review would be purely academic.

16. The SP&C Division has developed catalyst systems for DCPD reaction injection molding. At their request we provided information on the toxicology tests needed to support a PMN and the associated cost.

17. The saga continues with the Martha Mills Individual Cotton Exposure report for the first half of 1986. New work areas have been correctly entered, jobs reassigned to reflect time spent in these areas, new department and job numbers processed and all monitoring data received and cleared. The job averaging program was successfully executed but the intermediate update program failed twice - once due to a date sequence error in the program, then due to the requirement for a protection code indicator having been overlooked. Successful completion is expected by Oct. 3.

18. The HYTOX File (MSDS) now contains over 1,000 records with additions being made in excess of 100 per month, chiefly by Ms. Pearcy. Complete document sets have been provided to eight locations and we are close to providing complete documents to the other locations for which we have reasonably adequate inventory lists.

19. Ms. Dillon provided Gary Jones, Chemical Co., with additional printouts of PVC data from the EREF database.

20. Mr. Modrell consulted with Dave Stalnaker (Grantsville) regarding personnel exposure to MEK and THF at the Spencer Plant. Recent monitoring results were reported showing 2 of 9 MEK exposures above 100 ppm. The plant will continue to investigate the problem and perform additional monitoring.

21. Dr. Dietz testified in W. Virginia in a hearing involving allegations by the W. Va. Human Rights Commission of discrimination against a handicapped employee at the Union, W. Va. Plant.

22. Over 80 boxes of tissues, paraffin blocks, microscope slides and chemical test samples were received from Biodynamics. These are from the Curerite 18 and other studies. They must be kept indefinitely and will be stored at the Brecksville warehouse. Mr. Bachtel checked each box and spot-inventoried boxes of each type at Brecksville Receiving before they were taken to the warehouse. No discrepancies were found.

23. Medical schedules for five Goodrich locations and four Uniroyal-Goodrich locations were generated and distributed.

24. Cross-reference and class tables were updated three times this month.

25. Mrs. Wallace entered 4,898 records into the system this month.

Harold W. Dietz

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