

February 4, 1987

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

1. We have been notified of three cases of leukoderma at Robbins & Myers, Inc. (Springfield, Ohio). The Ohio Division of Safety and NIOSH have found that 2,4-di-tert-butyl phenol is present only in compounded rubbers (Burton Rubber) which contain Hycar 1052 and Nancar (Taiwan licensee version of Hycar 1052) and have identified DTBP as the probable etiological agent. As a result of these allegations, Dr. Hinderer has met with SP&C staff to discuss this problem and to determine a course of action.

We are particularly concerned that ODS and NIOSH have arrived at this conclusion without all the facts and through the use of inappropriate extraction procedures. Therefore, we are planning to get further information on recipes for the compounded rubber, the severity of the disease, and job histories and to analyze Hycar 1052, Nancar 1052, and the compounded rubbers.

2. We have become aware of apparent problems with the new "one pass" drying process for Carbopol 934-P. Although the "one pass" resin meets the monograph specifications, particle size, etc., a few customers have reported significant differences in time release characteristics, among others, as compared to the standard C-934-P. The product group questioned whether an FDA type product recall was required. We advised the group that no formal recall was necessary in this instance. However, customers who have received the "one pass" product should be informed and offered replacement with the standard C-934-P resin.
3. After submission of a proposed NF Carbomer monograph for Carbopol 1342, Mr. Bachtel received notification that all Carbomer monographs were on hold. The USP committee reviewing the monographs cannot resolve what to do about the residual benzene levels. If USP should decide to set unrealistically low residual benzene levels, it could cause significant problems for BFG and, in turn, benefit our competitors. Per USP's request, we have sent seven oral 90-day and 6 1/2-month toxicity studies on Carbopol 934 and 934-P. In addition, we sent the published Cosmetic Ingredient Review Expert Panel's safety assessment of the Carbomers.

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4. Procter & Gamble is replacing Carbopol 940 in Crest with Carbopol 934-P until a benzene-free resin is available. For P&G's use C934-P has been reidentified as Carbopol 940A. For labeling it is necessary to have a generic name assigned. Our original submission contained two possible crosslinkers. At the Cosmetic, Toiletry and Fragrance Association's (CTFA) request we have amended our submission to include only allyl ethers of sucrose. In light of this last request and the numerous present Carbomer names, CTFA is reviewing their future handling of such requests for new Carbomer designations.

The SP&C group has requested our assistance in developing studies for evaluating the toxicology of Carbopol EX-139 which is intended for toothpaste (P&G) and pharmaceutical use. Acute toxicity tests have been initiated and protocols for evaluation of the effects of repeated ingestion are being developed. These studies are estimated to cost approximately \$250,000.

5. Mr. Modrell consulted with the Troy Plant on details of conducting a plant-wide noise survey. Over sixty noise dosimeter measurements were obtained by the plant to reevaluate personnel noise exposure following reorganization and relocation of nearly all production areas. Data will be entered in the Medical Surveillance System.
6. A review of lead monitoring data for the Chemical Division's Terre Haute facility indicates high atmospheric lead concentrations. The situation was brought to the attention of Chemical Division management for correction.
7. The FDA has received between 200-300 letters and comments from environmental and political groups and the general public proposing the need for an Environmental Impact Statement of the Agency's PVC proposal. I reviewed the extensive SPI draft response and suggested some changes which were incorporated into SPI's final document.

Briefly, SPI has stated that FDA has correctly concluded that no EIS is needed; that FDA's proposal will not cause a significant increase in the use of PVC for food contact articles except for liquor bottles. SPI presented further evidence to refute allegations concerning adverse effects of PVC on solid waste disposal, incineration, recycling, etc. There is concern that in spite of the facts, FDA may react to undue political pressure and agree to an EIS. Such action could delay the Agency's final action on PVC for two to three years.

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8. Mr. Bachtel made an in-depth review of California Proposition 65 in relation to the FDA PVC proposal and EPA's recommended MCL for vinyl chloride in drinking water. From this review he concluded that PVC bottles for potable water in compliance with the FDA PVC proposal would be exempt from the warning and labeling provisions of Proposition 65. He sent a letter to Sparklets detailing his conclusions with an offer to perform extraction tests on commercial bottles as corroborative data. We are awaiting Sparklets' concurrence before starting studies. This could be a significant market for PVC compound.
9. Information was provided to Jon Hellerstein, Tremco, on an outside ventilation consultant (Bruce Menkel & Assoc.) to assist Tremco in assessing ventilation requirements to control employee nitrosamine exposures. Proper ventilation design must be arrived at for this new operation.
10. Mr. Modrell consulted with Dan Dimas on methods for controlling organotin exposures of A&DD field personnel. Monitoring equipment was provided for measuring personnel exposures.
11. Work continues on preparing MSDSs, entry into HYTOX and distribution to various facilities. The effort involves Ms. Dillon, Ms. Pearcy, Mr. Modrell and Dr. Dietz. The HYTOX database now contains 1,356 records. Quarterly updates and supplements were sent to 29 facilities including three UGT plants. Favorable feedback is being received, including requests for reports other than MSDSs. While the entry of new records slowed, we made progress in adding company identifiers and locations and in updating existing entries. The Kitchener Tire Plant requested a set of MSDSs and their location code was added to the appropriate file by Ms. Pearcy and several new entries were prepared to meet the request.
12. We have made a major effort, involving all department members to clean and reorganize our files to avoid moving unnecessary material to our new location.
13. Ms. Pearcy completed the task of identifying the facilities holding Occupational Health Policy manuals including the book number and current book holders. Updated material was sent to all but one facility.
14. We are continuing to assist the SP&C Division and a customer obtain potable water clearance for a product that uses Estane 5750. Discussions of recipe and extraction were held with the EPA contractor.

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