

H.W. Ditz

February 12, 1987

J. D. Ong

Activities Report - January 1987
Health & Environmental Services Division

Environmental Health

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 2,3-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, R. K. 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. After submission of a proposed NF Carbomer monograph for Carbopol 1342, W. C. 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~~4~~-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.
3. R. W. Modrell consulted with the Troy plant on details of conducting a plantwide noise survey. Over 60 noise dosimeter measurements were obtained by the plant to re-evaluate personnel noise exposure following reorganization and relocation of nearly all production areas. Data will be entered in the Medical Surveillance System.
4. 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.

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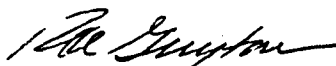
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Activities Report - January 1987
Health & Environmental Services Division - contd

5. 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. Dr. H. W. Dietz 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 liquid 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.

6. W. C. 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 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.
7. Work continues on preparing MSDSs, entry into HYTOX and distribution to various facilities. The effort involves C. Dillon, J. Pearcy, R. 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 files.
8. W. C. Bachtel met with representatives of Dow and DuPont in Wilmington to discuss a combined effort to gain FDA acceptance of polyether polyurethanes for repeated use food contact articles. It was agreed an industry effort would be more effective than separate petitions. A strategy plan and tentative timetables were developed. With the sharing of work by all three, we hope to file a petition with FDA by the end of 1987.



Richard A. Guyton

cc: L. Carter

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