

July 8, 1985

R. A. Guyton, M.D.

Subject: Environmental Health/Industrial Hygiene/Toxicology Activity
Report - June 1985

1. Progress was made toward implementing the use of BASIS by the groups for meeting OSHA hazard communication requirements. All three groups have agreed to use the system. The form and content of the material safety data sheets was finalized with group input. Necessary changes to the DDL have been defined and programming is underway.

We have received Battelle's proposal for implementation of a report to produce an internal MSDS which will enable us to meet the requirements of the hazard communication program. The proposal covers designing, programming and testing of the report.

In order to provide Battelle with some of the tools needed to accomplish this task, Mr. Katzenmeyer and Ms. Dillon held meetings with Sherrill Snedecker to review the necessary changes to the Hytox files data definition language (DDL). Once the DDL is updated, Ms. Dillon will enter 25 records into BASIS which will then be put on magnetic tape and forwarded to Battelle for testing purposes. After receipt of the tape, Battelle can then proceed with the project.

2. We are beginning to feel the impact of OSHA hazard communication in other ways as suppliers evaluate the hazards of materials sold to BFG. In determining whether or not a material poses a cancer hazard, OSHA has adopted those materials so identified by the International Agency for Research on Cancer (IARC). Some of our processing and extender oils are included in the IARC listing. Bob Hinderer and Mr. Katzenmeyer advised all product groups of this development. Whether or not products sold by BFG will require these oils is not resolved. Dr. Dietz and Mr. Katzenmeyer initiated a review through the RMA on this subject and we are working with the Tire Group on MSDS preparation and labelling to meet regulation requirements.
3. The Vinyl Institute primate and rodent studies at Southwest Research are proceeding as planned. We are waiting for delivery of some new equipment which will allow us to immediately know the exact concentration of HCl we are generating. This is particularly important as we complete exposures to the last two baboons in the 10,000 ppm group. We expect that the final baboon exposures and the first rodent exposures will begin in July.
4. The Curerite 18 male reproduction and dominant lethal studies are proceeding satisfactorily. Initial verbal reports on the dominant lethal study indicate that no evidence of a dominant lethal mutagenic event or excess pre-implantation loss was observed.

In an earlier dominant lethal study with CR-18 no dominant lethal effect was found, but an increase in pre-implantation loss was noted at the maximum tolerated dose. Because this increase was observed only in the first mating and not in the second and because the ranges for the two vehicle controls were wide, these events were considered the results of biological variability.

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4. (con't). The present dominant lethal studies provide further support that the observations in the earlier work were not the result of CR-18 administration.
5. We are working with the Chemical Group and Shell Oil in obtaining potable water clearance of an EPON/Estane system intended for use in relining decaying water pipes. The system is unique in that it can reline and seal pipe running under cities, rivers, etc. without excavation. If the health issues can be addressed satisfactorily, BFG and Shell will be able to penetrate a very large and lucrative market.
6. The Chemical Group has asked us to try to expedite toxicological evaluations on Goodrite 3150, an antioxidant/UV stabilizer. Submissions of PMN's will be needed in both the U.S. and the EEC countries. The toxicological evaluations to meet TSCA requirements are nearly complete and we advised the Chemical Group of the additional studies which will be needed to comply with the EEC 6th amendment.
7. The petitioned amendment to permit additional food contact uses of Goodrite 3114 was published in the Federal Register Monday June 3, 1985. This additional FDA approval permits the use of 3114 at a level of 0.1% in various olefin copolymer food contact articles. The petition was initiated by Shell Oil's need for a suitable anti-oxidant in a copolymer for Tupperware. Mr. Bachtel discussed the new clearance with several customers who expressed a keen interest in it.
8. We received notice from the FDA that our petition to permit additional uses of Goodrite 3125 in olefin copolymer food contact articles was accepted for filing. The first 90-day review period will be up on August 7, 1985.
9. In accord with our agreement with the USP-NF we have completed further work on the GC benzene method and a GC mass spectrometry method for total impurities in Carbopol. These will be submitted within the next month. Hopefully, these should fulfill the USP-NF needs so that monographs for the various Carbomers will be published. We have not, however, developed separate methods for residual monomers which USP-NF continues to discuss. We hope to persuade them that the GC-mass spec method for total impurities is a more meaningful test.
10. The FDA recently sent a letter to the US delegation of the Codex Alimentaries Commission (CAC) opposing new CAC work on standardizing food packaging laws and developing an international "positive list". A consultant to CAC had recommended development of a positive list similar to the US regulation for food packaging. Interestingly, the FDA's comments not only noted that such a move would be extremely expensive, time consuming and not easily accomplished, but that there is no public health concern to justify the effort. They indicated the regulatory problems faced by food packaging are administrative in nature and not justified by public health concerns.
11. Activity between MIS and Department 0020 has greatly increased as a result of an apparent effort to clear old system change requests for medical surveillance, resulting in a requirement to enter percentage of time spent on various cotton exposed areas by each job at Martha

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Mills and a reevaluation of the job cross-reference table to identify specific tasks in those jobs where exposures between tasks are significantly different.

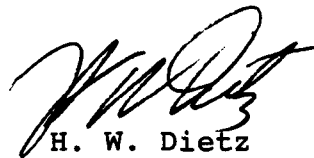
12. Dr. Hinderer has completed a second draft of a guideline to facilitate rational implementation of health assessment testing of indirect additives for potable water (i.e. ingredients for plastic pipe). The final document will be submitted to NSF who has been designated by EPA as the third party certifier in the potable water area.
13. The answer to the CPVC orange pigment dye problem has been found. Mobay has confirmed that the mutagenic response was due to another ingredient. They confessed that this ingredient was intentionally added by a technician to "work away" a small amount synthesized for R & D purposes. If Mobay had initially been more thorough in their record checking, \$30M worth of testing and numerous trips to NSF could have been avoided.
14. Negotiations are underway to find an alternate plant site for the ventilation research projects begun with the National Institute for Occupational Safety and Health (NIOSH). Marietta and Ft. Wayne have volunteered and Mr. Katzenmeyer has made arrangements for NIOSH to visit each plant to select a process. This work began in Akron, but with the shutdown of equipment we were using, necessitated looking for another location. Both we and general engineering feel the work will benefit BFG.
15. We received a copy of a letter from NIOSH to Michael Gaskill of Local 715 at Ft. Wayne advising the union of NIOSH's preliminary findings in the "investigation" of the union's concern over possible increased cancer in the milling and tubing area. This letter is very discouraging because without any real attempt to do any investigation, NIOSH says there may exist a possible excess of lung, eye and brain cancer as well as leukemia.

NIOSH made no effort to verify the accuracy of the diagnoses provided by the union, did not identify the entire population at risk and made statistical interpretations on ridiculously small numbers despite the fact that they had been advised that the diagnoses were not all correct and they did not have the complete population. For example, they found one eye cancer to be excessive and three brain cancers to be excessive when in fact there were no eye cancers and only one brain cancer in the list they were provided. The actual diagnoses in the other cases were pseudo tumors of the optic nerve and brain metastases from other sites. Although we will attempt to confer with NIOSH to correct these errors, the letter already written provides fuel for potential adverse publicity.
16. Dr. Dietz worked with D. Neale and K. Stimler to prepare a statement for submission to a California environmental agency defending the suitability of PVC and CPVC pipe for certain construction uses.
17. Dr. Dietz met with Mr. Norman Carr, an outside attorney, Mr. Hendricks and John McLaughlin and others to discuss a case against BFG alleging intentional tort in connection with exposure to TBTO at Plant 6. This suit is

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for 1.2 million dollars and is of greater concern because of a number of workers compensation claims which have been filed and which might lead to similar suits.

18. The Calvert City dispensary has requested and received medical listing and examination results from the medical surveillance system for all employees in D/5728. Additionally, 18 other reports were requested by other company segments. These requests were all satisfied within 48 hours. Also, medical exam schedules were generated and distributed to the eight locations now using them.
19. Mr. Katzenmeyer visited the Tremco Columbus plant to investigate an industrial asthma case in their mold department. A report has been issued recommending ways of managing this case. Considerable analytical work and costs were expended to date, some of which were not necessary and which could have probably been avoided had we been involved earlier.
20. Ms. Wallace entered 5,041 records in to the medical surveillance system during the month.



H. W. Dietz

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