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MONSANTO INDUSTRIAL CHEMICALS CO.
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December 14, 1981

Mr. William Gunter
U.S. ENVIRONMENTAL PROTECTION AGENCY OTS
401 M Street, Southwest
Washington, DC 20460

Dear Bill:

During our recent discussion of health and toxicity effects of PCB's with Dr. Todhunter, the question of the significance of cirrhosis findings in the Brown and Jones studies was raised. I asked Dr. W. R. Gaffey, who is Manager of the Epidemiology Section of Monsanto's Department of Medicine and Environmental Health, to comment on these findings in more detail than in his review paper. Attached for your information are his comments.

I hope these will be helpful in your review.

Yours truly,

John H. Craddock,
Product and Environmental
Safety Director

jb
enclosure

PS: Dr. Gaffey has had "hard xerox copies" of the references in his paper prepared for use by Dr. Carlton Nadolney of your staff. These will be shipped by Federal Express today. JHC

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W. R. Gaffey Dept. of Medicine & Environmental Health G2WE 4-8811

DATE December 8, 1981

SUBJECT Cirhhosis mortality in capacitor workers

REFERENCE

TO J. H. Craddock - A2SA

You requested my comments on the excess mortality from cirhhosis of the liver that was observed by Brown and Jones [1] in their mortality study of capacitor workers. They found six deaths where 5.47 were expected. The excess was concentrated in one of the two plants studied, with five observed where 3.1 would be expected. The excess showed an increase with duration of employment, but an ambiguous relationship with latency. The numbers were small, and none of the excesses was statistically significant.

I do not think these findings are of substantive importance for several reasons. First, not only are the excesses not statistically significant, but the expected values for the plant in which there was an excess are so small (below 5) that many practicing epidemiologists do not consider that a test of significance is valid for such data. Second, at least three of the six cases had a history of alcohol consumption. Third, although the other studies references by Brown and Jones are small ones, they do not confirm the finding. Finally, a fairly large study of Italian capacitor workers by Bertazzi et al [2], which was not known to Brown and Jones when they published, did not report any cirhhosis deaths.

I cannot deny the possibility that a very large study with long latent periods might find an important excess of cirrhosis (or indeed of any other cause) but, considering the small numbers, the ambiguity of the pattern, and the lack of confirmation, I see no reason for concern about cirrhosis on the basis of the current data.

William R. Gaffey

William R. Gaffey

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References

1. Brown, DP and Jones, M. Mortality and industrial hygiene study of workers exposed to polychlorinated biphenyls. Arch. Envir. Health 36:120, 1981.

2. Bertazzi, P. et al. Mortality study of male and female workers exposed to PCBs. Int. Symposium on Prev. of Occup. Cancer, Helsinki, Finland April 21-24, 1981.

MONS 003605

IN 10M (REV 2/78)

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2. Bertazzi, P. et al. Mortality study of male and female workers exposed to PCBs. Int. Symposium on Prev. of Occup. Cancer, Helsinki, Finland April 21-24, 1981.

MONS 003606

IN 10M IRLV 2-781