

AV 7773
6/1/80

TO: W. C. HOLBROOK

DATE: APRIL 30, 1980

FROM: R. K. HINDERER

SUBJ: APRIL 1980 PROGRESS REPORT

1. Dominant Lethal Assays.

The repeat of the Dominant Lethal Assay (whole animal mutagenic assay) on Cure-Rite^R 18 has begun. This repeat study is necessary because of contractor error. The repeat has allowed us to use more precise dose levels and will help in establishing dose levels for a long-term chronic toxicity/cancer bioassay. This study will be completed in June.

The OBTS, methylnorbornene, and methyltetracyclododecene repeat studies will begin in the near future.

2. Cure-Rite 18.

Range-finding studies on Cure-Rite 18 are nearly complete. We are waiting for the final approval to proceed with the long-term feeding study.

3. Ciago Visit.

The purpose of this visit was to review specific programs and to enhance communication and coordination between the Ciago Industrial Hygiene Group and the Toxicology and Environmental Affairs Department. The discussions were extremely beneficial and led to numerous items for follow-up. A copy of the minutes of these meetings will be provided shortly.

4. Food and Drug Activity in Europe.

The purpose of my trip to the British Industrial Biological Research Association (BIBRA) and part of my Ciago visit was (1) to determine who could best handle our future and present food and drug application needs in Europe, and (2) to work out some specific details of a contract for the monitoring of a long-term feeding study in France by BIBRA. As the result of the meeting, we (Bert ter Muelen, Harvey Higgenbotham, and I) felt that BIBRA could best assist us in obtaining food and drug approvals in Europe, with the exception of the Netherlands and West Germany which can be handled by C. van Helden and Dr. Hofman, respectively. Since BIBRA has done an excellent job of monitoring the IISRP/Butadiene inhalation study and I have worked closely with them, they were clearly the first choice for this latter area.

5. IFREB Site Visit.

During my trip to Europe, I visited the French Institute of Research and Biological Tests (IFREB) in order to assess their capabilities and to discuss a long-term feeding study protocol which I had provided earlier. I was generally pleased with what I saw and felt that they could conduct a study which would be acceptable to both U.S. and European food and drug regulatory agencies.

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6. EDC.

Sponsors of the EDC Pharmacokinetic studies met at the Dow Chemical Company. The interim data did not show any major differences between oral and inhalation routes of exposure, except for exceedingly high peak blood levels via oral administration. DNA regeneration and macromolecular binding studies will be completed by the end of June.

7. PPFA Meeting.

I provided comments on a protocol to evaluate the potential exposure to solvents in potable PVC-solvent cement water systems. No decision was made on conducting a literature search on the toxicity of these solvents.

8. SPI/PVC Safety Group Meeting.

Maurie Johnson asked me to attend an SPI meeting in his absence. We discussed the submittal of comments to OSHA on their recent request for information on VCM/PVC.

9. Surpon PMN.

The PMN for Surpon A-313 is now in the internal review process. We plan to submit this during the first part of May.

10. VCM/CMA.

The Vinyl Chloride Project Panel has decided (1) to conduct histopathologic examination of the brains of animals that Industrial Bio-Test Laboratories failed to do, and (2) to attempt to validate chamber exposures. This work will be undertaken because of concerns raised involving TOSCA/8e reporting and the brain tumor controversy in Texas.

11. TOSCA Initial Inventory.

We received notices from EPA concerning confidentiality claims and generic names in some of our submissions for the Initial Inventory. We responded immediately to EPA on one since this was covered by an earlier resubmission.

We are waiting for new generic names to be provided. We expect to reply to EPA on these other forms within the next two weeks.

12. Acrylate Toxicity Seminar.

Steve Mann attended a presentation at ALTC by Celanese on several acrylates. He also learned that Celanese has prepared a film to educate workers which he will send for our review.

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13. Mutagenic Screening/Worker Education.

Dr. Golberg informed me that the CIIT Executive Committee rejected our request to have CIIT coordinate and assist in developing an industry-supported film to educate the workers on mutagenic screening. The group concluded that "such a film would constitute advocacy on the part of CIIT". Dr. Golberg suggested that we work through CMA.

14. TOSCA 8(a) Recordkeeping and Reporting Rule.

We are continuing to review the EPA list of 2,300 chemicals to determine potential reporting requirements.

15. Latex Support.

At the request of the Latex group, we have had discussions with P&G scientists in order to satisfy their needs and concerns.

COMING ATTRACTIONS

CMA/Rubber Chemical Panel - to review and develop studies on rubber chemicals

CMA/CRAC Quarterly Update Meeting

MISCELLANEOUS ACTIVITIES

TOSCA 8(a) and 8(c) - Review of proposed and draft rules

Combustion Toxicology - NBS status report review

MSDS reviews

Literature searches

Estane MDA Task Force participation

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H. Higgenbotham

J. Weisel

T. Bhe

S. Esakov

C. van Helden/H. Slooten/Dr. Hofman

W. C. Becker

R. W. Strassburg

H. J. Fast

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H. H. Waltemate

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E. W. Shaw

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C. S. Stambolos

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J. B. Nolan

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R. D. Savage/A.M. Luxeder/J.R. Goots

R. A. Krueger/R&D Directors

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