

EXHIBIT 32

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ORTHO DIVISION
RESEARCH AND DEVELOPMENT DEPARTMENT
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MEETING REPORT: CHEVRON-IBT LIAISON MEETING

A meeting was held with IBT on November 17th in the Richmond Conference Room. Present at the meeting were: Chevron - D. F. Dye, F. X. Kamienski, J. N. Ospenson and L. R. Stelzer (H. G. Franke and B. V. Tucker present for part of meeting); IBT - M. L. Keplinger; and SOCAL - R. D. Cavalli. A copy of the agenda is attached. The highlights of the meeting are outlined below. Items requiring action are underlined.

1. CAPTAN

A. General

Our current information is that the Criteria and Evaluation and Registration Divisions of EPA are not particularly concerned about Captan. EPA seems to be avoiding the mutagenic issue since they don't know how to handle from a regulatory standpoint. However, the Health Research Group and other environmentalists are relating mutagenic materials as being potential carcinogens. IBT reports that to their knowledge, studies at the National Cancer Institute have not developed any positive cancer data on Captan and the report is now being prepared. IBT's chronic rodent studies are negative for carcinogenic potential.

B. Rosenkrantz, Collins' and Bridges' Reports

The recent tumorigenic study by Rosenkrantz, Collins' dominant lethal study and Bridges' review article, although outwardly damaging to Captan, apparently have not raised any serious questions within EPA. The validity of Rosenkrantz's findings are questionable - it is our opinion that currently there is no evidence that animals treated with Captan had an increased incidence of tumors. Bridges' review relied heavily on Collins' work to emphasize the mutagenic potential of Captan. The fact that Collins destroyed his raw data weakens Bridges' position on the mutagenic potential of Captan. However, Bridges raises serious questions on the safety of Captan and suggests studies to evaluate the safety of Captan. The information and questions presented by Bridges are not new to us and we have proposed studies to respond to his criticisms by considering the "defense toxicology" program outlined below.

C. Defense Toxicology

There was agreement on a "defense toxicology" program which would allow an in-depth evaluation of the safety of Captan. These studies will be initially supported by Chevron. However, we will discuss this program with Stauffer in a January 1976 meeting and ask for their participation on a cost-share basis. The defense toxicology studies agreed upon are as follows:

1. Dietary Subacute Dominant Lethal Study (Mice)

Phase I and II portions have been completed. Diet stability studies of Captan in mouse and rat diets are in progress. Following completion of the dietary stability study, the Phase III portion of the study will be initiated. Stauffer has agreed in writing to support this study on a 50:50 cost-share basis.

F. X. Kamienski will include provisions in the Phase III protocol for dietary analysis for Captan after each weekly diet mixing to determine distribution, and spot-check analyses at selected weekly intervals to determine diet stability. It was also agreed that in all future subacute, chronic and specialized dietary toxicology studies, the protocol will provide for analyses after diet mixing for compound distribution and spot-check analyses at selected intervals for diet stability evaluation.

2. Wildbird Reproduction Study

Hen pheasant reproduction studies have been completed for a PhD thesis at Michigan State University using captan-treated corn at recommended label rates. F. Kamienski discussed the findings with Dr. Prince, the project coordinator, in a November 17 telephone conversation. Dr. Prince concludes from these studies "that based on the function that Captan serves, there is no reason to believe that Captan is hazardous to pheasant under use conditions". It appears that Dr. Prince's studies will satisfy the data gap for a wildbird reproduction study. F. X. Kamienski will obtain a copy of Dr. Prince's work. Wildbird reproduction studies will be withheld pending a review and evaluation of Dr. Prince's findings.

3. Subacute Inhalation Studies

SOCAL will initiate pilot 90-day inhalation studies with micronized technical products of Captan, DIFOLATAN and PHALTAN as background data for 2-year inhalation studies. Blood and bone marrow cytogenetic analyses will be included in the protocol. These studies are designed to evaluate plant worker-hazard exposure. SOCAL will prepare protocols for review and comment within the next two weeks.

4. Feasibility Study

SOCAL will conduct a feasibility study to determine if a human population is available in our Captan formulating/manufacturing plants for a meaningful epidemiological study and cytogenetic survey. J. A. MacGregor is to outline a program prior to our January meeting with Stauffer. Approval from D. B. Barlow, legal and manufacturing must be obtained prior to initiating actual survey work. If a suitable population is available in Ortho or Chevron/France plants, Stauffer will be excluded from participation.

D. B. Barlow is scheduled to visit Chevron/France in early December. J. A. MacGregor should provide J. N. Ospenson with a list of the type of information she would need by November 30 so he can review with Barlow on December 3.

5. Translocation Mutagenic Assay

Stanford Research Institute is conducting dietary subacute translocation studies with Captan and PHALTAN in mice under EPA contract. The SRI studies are methodology studies designed to improve the state of the art. Although the translocation mutagenic assay is suggested as a requirement in the EPA Guidelines for Registering Pesticides, we will withhold a translocation study until the SRI studies are completed and reviewed. The SRI studies are EPA sponsored - the results will be available to us. IBT does not expect Captan to be positive in the translocation assay.

6. Publication of Chronic Mouse/Rat Studies

It was agreed that the chronic mouse and rat studies would be useful in assisting others in obtaining a "me-too" registration and, therefore, should not be published at this time. However, IBT will prepare a "final draft" of these studies for publication review but publication would be withheld until the registration situation is clarified. D. Barlow's approval must be obtained for all publication of Chevron data.

7. 3-Generation Reproduction Study

A question was raised on IBT's method of "random selection" of animals in the original rat reproduction study. IBT is reviewing the method of animal selection in their reproduction studies and will supply Chevron information demonstrating that selection of animals was "random".

8. Cytogenetic Evaluation - Animal Dietary Studies

No intention at this time to initiate dietary feeding studies for cytogenetic evaluation. This project would be pursued only if subacute inhalation studies show adverse effects.

9. Comparative Bacterial Mutagenic Assays

Comparative bacterial mutagenic assays on Captan, DIFOLATAN and PHALTAN were not considered necessary.

10. Chronic Beagle Dog Study

IBT felt that EPA is not requiring this information for Captan. The 1 year beagle dog study appears adequate to satisfy EPA requirements for registration.

11. Review of Captan Tolerances

It was agreed that current U. S. tolerances on Captan may be higher than necessary. It was agreed that a program should be set up to obtain more residue data at least on some of the more important crops. This information will be necessary when EPA decides to bring the U.S. tolerances in line with the Codex tolerances.

2. DIFOLATAN

A. WHO Toxicology Data Request

IBT does not understand the WHO basis for requesting clarification of the histopathological changes in the kidney and liver of rats and the lymphocyte-neutrophil shift noted in the 2-year chronic oral and the target-organ studies. IBT indicated that no-effect levels had been established in both studies and the target-organ study utilized extremely high levels to illicit an effect. IBT will prepare a critique of current DIFOLATAN studies for WHO indicating that the data submitted are adequate to make a hazard evaluation and that further toxicology studies are not necessary.

WHO also requested additional toxicology data on Captan. Keplinger recommended, and we agreed, that since these data are only "desired" we should not run any studies until they are "required".

B. Subacute Monkey Study - 4F

IBT has agreed to rerun the monkey inhalation study at their own expense. Instead of merely repeating the study, the protocol should be revised to include parameters that would provide information to the Threshold Limit Value Committee to raise the proposed TLV of 0.1 mg per cubic meter. IBT will still pay for a portion of the revised protocol. F. X. Kamienski and R. D. Cavalli will generate a protocol to reflect industrial hygiene parameters and send to IBT for review and comment. SOCAL will request TLV Committee for their data base used in proposing a TLV of 0.1 mg per cubic meter.

3. PARAQUAT

A. Rebuttable Presumption

EPA's earlier activity of a rebuttable presumption against Paraquat for lack of antidote or palliative treatment appears to have subsided. Chevron has done everything possible to prepare a basis for argument. R. D. Cavalli feels we have a reasonable case for defending a Paraquat rebuttal and our position will improve with time. SOCAL will ask PPD to continue documenting poisoning and recovery cases. PPD is proposing additional animal studies to further define the effectiveness of absorbent clays and cathartics in overcoming lethal effects of small but fatal doses of ingested Paraquat.

B. Sucrose Octaacetate

A taste panel study will be proposed by Chevron and SOCAL to evaluate the addition of sucrose octaacetate as a deterrent to ingestion. IBT will not be involved. F. X. Kamienski will review the toxicology literature prior to initiating human taste panels. The use of sucrose octaacetate as a deer or animal repellent product was suggested. F. X. Kamienski will review the literature to determine if sucrose octaacetate was previously tested as a deer repellent agent. Technical Coordination will propose potential deer, dog or other animal repellent usage to G&H Research.

C. Valeric Acid

Chevron still wishes to obtain an exemption for the requirements of a tolerance for valeric acid when used up to 2% as a stench agent. IBT will prepare a registration package and petition EPA/FDA for an exemption - Chevron considers this program a high priority item.

4. RE-19790 - Development Program

IBT agrees with our proposed toxicology program if a development decision is reached. Based on structure of 19790 and proposed metabolites, IBT does not see any toxicology problems but cautions that only animal tests can adequately define any potential problems. IBT advises not to start long term toxicity studies until residues and metabolites are defined. Keplinger pointed out that 90-day subacute studies are adequate to support a temporary tolerance petition - interim 1-year-reports from chronic studies are not needed. By the next liaison meeting Chevron should have a development commitment and additional residue/metabolism questions for discussion with IBT.

5. Toxicology Costs

IBT anticipates costs to increase 6-10% per year barring any unforeseen economic events.

6. Chlordane/Heptachlor Hearings

The interpretation of pathology appears to be the key problem and the feeling is these materials will be banned. EPA's 17 cancer principles have not been accepted by the scientific community. A National Cancer Institute subcommittee is attempting to define "cancers" and appear to take the position that there are differences between benign and malignant tumors - this offers some hope for a scientifically acceptable definition of a tumor. Keplinger indicates that endrin, BHC/lindane and toxaphene will probably face cancellation/suspension hearings.

7. BOLERO - Duck Reproduction Studies

Adverse findings were reported for several parameters. Chevron's intention is to prepare a hazard evaluation supporting the position that under use

conditions, the hazard to waterfowl is minimal - this information will be submitted with our tolerance petition. Kamienski will formulate the hazard evaluation - IBT might be asked for assistance.

There were no further items of discussion.

Submitted by

F. X. Kamienski

F. X. Kamienski

FXK:mab

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