REPORT

AD HOC PLANNING GROUP ON PHTHALATE STUDIES

I. INTRODUCTION

As a result of several press accounts of potential health problems arising from phthalate esters in the environment, a meeting of representatives of interested MCA member firms was held on February 24, 1972.

Although there appeared to be no reason for immediate or undue concern, it was recognized that a careful review of pending environmental and toxicological questions should be considered. At this meeting an Ad Hoc Planning Group was formed to recommend a program for this purpose, as follows:

Monsanto Company	P. R. Graham, Chairman
Eastman Kodak Co.	R. L. Raleigh, M. D.
Enjay Chemical Co.	J. R. Livingston
Union Carbide Corp.	L. G. Krauskopf
U.S.S. Chemicals (Div. of U.S. Steel)	J. S. Mackay
Baxter-Travenol Labs.	R. M. Gesler (now N.J. Kartinos)
Borden, Inc.	A. S. Cummin
W. R. Grace	A. B. Magram
Tenneco Chemicals, Inc.	T. R. Aalto (recent member)
MCA Staff	G. E. Best

The foremost objective of the Ad Hoc Group is to recommend an action program concerning the pending phthalate environmental and toxicological questions.

To achieve the above objective, the following categories were studied -- see reports attached:

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1. Toxicological

   a. Oral Ingestion
   b. Metabolic Fate
   c. Teratology
   d. Inhalation, Skin Absorption and Intraperitoneal Injection
   e. Intravenous Injection

2. Ecological and Environmental

   a. Natural Occurrence
   b. Biodegradability
   c. Environmental Contamination

3. Industrial Hygiene

4. Regulatory Agency Liaison

II. STATUS

Toxicological - The preponderance of the data collected by the group was, as expected, concerned with the oral ingestion of phthalates. Extensive chronic, sub-acute and acute oral studies have shown the phthalates to have a very low order of toxicity. While the lowest molecular weight homologs, dimethyl-, diethyl- and dibutyl- were shown to be a little more toxic than the higher molecular weight members of the family, none of these low molecular weight compounds were shown to be hazardous by this route.

There are insufficient data available to permit generalizations regarding the metabolic fate of phthalate esters. The existing information relating to teratogenicity of phthalates or of their long-term toxicity via vapor inhalation, skin absorption and intravenous injection is

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inconclusive. Low orders of acute toxicity for the higher homologs (C_7-C_9) have been demonstrated for room temperature vapor inhalation and for intraperitoneal injection. Investigations are underway to answer some of these questions.

Ecological - Evidence exists pointing to the natural occurrence of phthalates. However, these natural sources do not appear to explain the ubiquity of phthalates in the environment. It is probable that phthalates enter the environment from sources other than plastics, namely, munitions, insecticide formulations and cosmetics. Phthalates are not readily biodegradable but are far less persistent than PCB's or DDT.

Industrial Hygiene - All companies contacted have reported no adverse effects on their employee population as a result of phthalate exposure. Phthalate esters have been manufactured by some of these companies for over 30 years.

Government Agency Activity - We understand that the FDA is not considering any changes pertaining to phthalates in their regulation because insufficient evidence is in hand to warrant such a change. The Environmental Protection Agency, the National Institute of Health and the National Institute of Environmental Health Services have active projects through academic grants and in-house studies. The Council on Environmental Quality is monitoring the phthalate question. No Congressional action is contemplated at this time.

III. RECOMMENDATIONS FOR PROGRAM UNDER MCA ADMINISTRATION

Short Range

1. **Disseminate available oral toxicity data and natural occurrence evidence on phthalates in conjunction with:**

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-- FDA Food Additives Section

-- National Institute of Environmental Health Sciences meeting in September, 1972

-- SPE Meeting - March 1973. Regional Technical Meeting on the subject.

2. Retain a competent consultant to critique all available information. This consultant would help in any planning future MCA sponsored studies.

3. Assess $1,000 per company to cover costs of consultant(s) and other expenses related to these publication of our data.

Long Range

1. Publish the data relating to metabolism, teratology, vapor inhalation, skin absorption and intravenous injection when existing projects are complete.

   -- Baxter-Travenol Intravenous Injection study with Johns-Hopkins. This will include metabolism via intravenous route.

   -- Enjay study of DINP metabolism.

   -- Monsanto vapor inhalation study now in progress.

   -- University of Tennessee and Johns-Hopkins phthalate metabolism study via vapor inhalation and oral routes.

2. Sponsor detailed study of teratology, mutagenicity and carcinogenicity of phthalates.

3. Complete skin absorption study.

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4. Seek answers to the following questions concerning the presence of phthalates in the environment.

   -- How did the phthalate moiety get there?

   -- What effects from their presence are verified?

   -- If necessary, how can we effectively reduce the amount entering the environment?

5. Continue the present Ad Hoc Group steering committee for surveillance of the program.

6. Provide financial support for required programs.

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