UNION CARBIDE

CHEMICALS AND PLASTICS

N. L. ZUTTY
TEL. (212) 551-6557

DATE:

(1) ~~R S Hanna~~
(2) R N Wheeler

FYI

NZ. (last).

270 PARK AVENUE, NEW YORK, N. Y. 10017

RECEIVED
FEB 28 1974
N. L. ZUTTY

SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE • NEW YORK, NEW YORK 10017 • 212/687-2675

February 21, 1974

Mr. V. L. Larson
Union Carbide Corporation
Chemicals & Plastics
270 Park Avenue
New York, New York 10017

Dear Vern:

THE FDA's PRIOR SANCTION OF PVC IS IN JEOPARDY UNLESS YOU ACT AT ONCE!

This is not a "scare" headline to attract your attention. The FDA has raised a question about the carcinogenic effects of VCM used in PVC packaging, and it wants S.P.I. to provide it with toxicological data. The attached report which was prepared by a special task force chaired by Art Sheldon of M & T spells out in detail what is needed.

Should the FDA withdraw the prior sanction, the fallout of this action upon PVC products other than packaging could be substantial. The expanded vinyl used as seating in automobiles and furniture could come under attack. PVC pipe would probably be attacked by its metal pipe competitors.

Realizing that the present situation affects the entire PVC industry, Ken Michel, Chairman of the Ad Hoc PVC Liquor Bottle Committee, in consultation with S.P.I., has proposed that a separate ad hoc committee be established to monitor the proposed testing. It is only logical that PVC resin producers staff this committee. The bottle producers are primarily interested in the 90 day feeding test. Of course, some fabricators have a large interest in PVC packaging and they may wish to support the two year study.

We cannot emphasize the need to move ahead with the feeding studies just as soon as possible. In order to avoid delay by trying to determine upon what basis we should assess four different classes of interest, we propose that you indicate on the attached form your degree of interest in the PVC industry. S.P.I. will then equitably assess you on the basis of your reply. We estimate your maximum share would be $8,000 to $10,000 for the two year study. The cost will be spread over a two year period.

Dr. C. M. Neher, Ethyl Corporation, has been asked by S.P.I., and he has agreed to chair this new Ad Hoc committee. The Ad Hoc PVC Liquor Bottle Committee, with the formation of this committee, will stay in existence, but will discontinue further work in this area. Should the new ad hoc committee need their assistance, the Ad Hoc PVC Liquor Bottle Committee will convene. Assuming that this will not be needed, we anticipate that the Ad Hoc PVC Liquor Bottle Committee will not have to meet until the new ad hoc committee has completed the 90 day feeding studies and it is ready to report its findings.

Please complete the form and return it no later than March 1, 1974. The FDA is waiting for our response. Should you have any questions, please contact me. If we don't hear from you by March 1, you'll hear from us.

Cordially,

Thomas J. McGrath

Thomas J. McGrath
Director of Packaging Services

TJMcG/pb

enc.

THIS LETTER WAS SENT TO THE FOLLOWING INDIVIDUALS:

Mr. Herbert J. Kandel
American Chemical Corporation
P. O. Box 9247
2112 E. 223rd Street
Long Beach, California 90810

Mr. R. J. Ventres
Borden Chemical Company
50 West Broad Street
Columbus, Ohio 43215

Mr. Harry E. Connors, Jr.
Diamond Shamrock Chemical Co.
Diamond Shamrock Bldg.
1100 Superior Avenue
Cleveland, Ohio 44114

Dr. C. M. Neher
Ethyl Corporation
Plastics Division
451 Florida
Baton Rouge, La. 70801

Mr. T. C. Walker
Firestone Plastics Company
P. O. Box 699
Pottstown, Pa. 19464

Mr. Jean F. Malone
B. F. Goodrich Chemical Co.
6100 Oak Tree Blvd.
Cleveland, Ohio 44131

Mr. W. F. Christopher
Hooker Chemical Corporation
1515 Summer Street
Stamford, Connecticut 06905

Mr. Jack Jaglom
The Pantasote Co. of New York
26 Jefferson Street
Passaic, New Jersey 07055

Mr. H. W. Nolte
Stauffer Chemical Company
Plastics Division
Westport, Ct. 06880

Mr. G. E. Disch
Tenneco Chemicals, Inc.
Intermediates Division
P. O. Box 2
Turner Place
Piscataway, New Jersey 08854

Mr. V. L. Larson
Union Carbide Corporation
Chemicals & Plastics
270 Park Avenue
New York, New York 10017

Mr. S. Salem
General Tire & Rubber Co.
Chemical/Plastics Division
P. O. Box 951
Akron, Ohio 44329

Mr. R. E. Workman
Goodyear Tire & Rubber Company
1144 E. Market Street
Akron, Ohio 44316

Mr. Curtis W. Collyer
Olin Corporation
Designed Products Division
120 Long Ridge Road
Stamford, Ct. 06904

Mr. Robert L. Knapp
Uniroyal Chemical Division
Uniroyal, Inc.
Spencer Street
Naugatuck, Ct. 06770

Dr. A. R. Adams
Air Products & Chemicals, Inc.
Five Executive Mall
Swedesford Road
Wayne, Pa. 19087

Mr. John E. Ertel
Robentech
1407 Texas Street
Fort Worth, Texas 76101

Mr. J. F. Gabbett
Conoco Chemicals Company
Continental Oil Company
Park 80 Plaza E
Saddle Brook, New Jersey 07662

Mr. Karl A. Hochschwender
American Hoechst Corporation
Route 202 - 206 N
Somerville, New Jersey 08876

Mr. Alex Kaufman
W. R. Grace & Company
Hatco Chemical Division
P. O. Box 27
Fords, New Jersey 08863

Mr. W. J. Vogel
Reynolds Metals Company
Packaging Division
6601 W. Broad Street
Richmond, Va. 23261

Mr. Joseph L. Downey
The Dow Chemical Company
2040 Dow Center
Midland, Michigan 48640

Mr. K. L. Mai
Shell Chemical Company
Div. of Shell Oil Co.
Polymers Division
P. O. Box 2463
Houston, Texas 77001

Mr. D. P. Wedell
PPG Industries, Inc.
One Gateway Center
Pittsburgh, Pa. 15222

Mr. Jack L. Shafer
Marbon Division
Borg-Warner Corporation
P. O. Box 68
Washington, W. Va. 26181

Mr. Martin F. Bretl
Rohm & Haas Company
Independance Mall W.
Philadelphia, Pa. 19105

Mr. J. N. Koral
Cincinnati Milacron Chemicals, Inc.
West Street
Reading, Ohio 45215

Mr. M. Kohno
Kaneka America Corporation
919 Third Avenue
New York, New York 10022

Mr. Al Keller
M & T Chemicals
Rahway, New Jersey 07065

Mr. Frank M. Harris
Aim Packaging, Inc.
Erie Industrial Park
Port Clinton, Ohio 43452

Mr. William J. Smith
American Can Company
American Lane
Greenwich, Connecticut 06830

Mr. William E. Risch
Anchor Hocking Corporation
189 Container Place
Springdale, Ohio 45246

Mr. Kenneth J. Auer
Celluplastics, Inc.
55 North Street
Fitchburg, Mass. 01420

Mr. Kenneth G. Michel
Continental Can Company, Inc.
Plastics Container Division
633 Third Avenue
New York, New York 10017

Mr. L. L. Otterson
Dura-Containers, Inc.
3424 West 48th Place
Chicago, Illinois 60632

Mr. Robert P. Kittredge
Fabri-Kal Corporation
3303 E. Cork Street
Kalamazoo, Michigan 49001

Mr. D. E. Paxson
Kerr Glass Manufacturing Corp.
Packaging Products Division
P. O. Box 4000
Lancaster, Pennsylvania 17604

Mr. Clement J. Cornay
Marquis Products Co., Inc.
931 E. Convent Street
P. O. Box 52452
Lafayette, La. 70501

Mr. C. Malcolm Cooper
Owens-Illinois, Inc.
Plastic Products Division
P. O. Box 1035
Toledo, Ohio 43601

Mr. J. P. Bennett
Trio Products, Inc.
250 Warden Avenue
Elyria, Ohio 44038

SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE • NEW YORK, NEW YORK 10017 • 212/687-2675

RETURN NO LATER THAN MARCH 1, 1974 TO:

Mr. Thomas J. McGrath,
Director of Packaging Services
The Society of the Plastics Industry, Inc.
250 Park Avenue
New York, New York 10017

1. Our company has an interest in VCM ( ), PVC resins or compounds ( ), additives used in PVC ( ), PVC packaging ( ).
(please check areas of interest)

2. We will support the:
   a. 90 day feeding test ( )
   b. 90 day feeding test in tandem with a two year feeding test ( ).

3. We wish to participate on the ad hoc committee ( ). Our representative will be _____ (name). We understand that our maximum financial obligation will not exceed $10,000.

NAME OF COMPANY _____

ADDRESS _____

_____

AUTHORIZED SIGNATURE _____

Report of Ad Hoc Liquor Bottle Committee Task Group

The Task Group met on January 24, 1974 to consid r the problems involved and to attempt to develop a protocol for a feeding study for vinyl chloride monomer (VCM). The Committee is recommending that a 90-day feeding study with rats be conducted, in tandem with a lifetime feeding study (two year study) for the reasons discussed subsequently. The Committee is also providing details about alternate test possibilities.

The major problem involved in devising a feeding study for VCM is that the monomer is a gas at room temperature, volatilizes rapidly from conventional feedstocks, and thus poses a problem in determining exactly how much material the animals are eating. There is no problem in getting the animals to eat some vinyl chloride monomer but for a well controlled feeding study it is essential to feed known quantities at different dietary levels, and it is to proposals for the solution of this problem that the Task Group directed its first attention.

The following chart shows the several possible ways in which the vinyl monomer might be incorporated in the rat diet in a measurable way:

Method	Comments
Directly into food	Possible chemical reactions
Dissolve in oil and encapsulate	Oil loses VCM rapidly
Dissolve in water	Soluble to about 1%; does not evaporate quickly
Direct intubation	Possible for 90-day study
Absorption on Activated carbon	Holds VCM without loss

In evaluating these possibilities, the attempt to incorporate vinyl monomer directly into food was rejected because of the possibility of unknown chemical reactivity.

Although it was found that the vinyl monomer evaporated rather rapidly from edible oil in preliminary tests, the possibility of developing a suitable encapsulation technique whereby

oil saturated with monomer could be encapsulated in a coating through which the monomer could diffuse at a known rate should be considered.

The monomer was found not to evaporate very rapidly from closed water systems but the problem connected with the rate of monomer evaporation from the exposed drop at the end of the rodent sipper tube will require careful study. Furthermore, there is a question as to whether sufficient monomer can be administrated via water, but here the possibility exists that the solubility of the vinyl monomer in water may be increased through the use of some harmless additive.

The possibility of employing direct intubation involves a technique which has been used, but which poses well known problems of animal trauma which may complicate the interpretation of any results. Furthermore, this technique is considered of only dubious value for a possible long-term study.

The final suggestion involved the absorption of vinyl monomer on activated carbon and the administering of such carbon as the source of dietary VCM. This approach has been shown to be feasible for administering large quantities of VCM, but it remains to be shown whether the VCM absorbed on carbon will be biologically available to the rats, i.e. whether the VCM will be desorbed from the carbon after the animal has eaten the material. Here the possibility exists that carbons of varying absorptive power and ease of release may provide a useful balance of properties to make the approach practical and useful.

The first recommendation of the Task Group is that the carbon absorption procedure be investigated with particular respect to the quantity of VCM that could be administered and the rate of desorption. This can be done initially in vitro with final confirmation assured by direct feeding studies with a radio-carbon tagged VCM.

A second screening approach that is recommended for study involves the use of water or water plus an additive. This should be studied by monitoring the evaporation rate from the exposed droplet, with consideration being given to the total amount of VCM that can be administered. Here again after the in vitro studies have been completed, the results should be confirmed by feeding studies with a radio-labeled sample of VCM.

A third possibility will involve encapsulation of an edible oil containing dissolved VCM. The feasibility of this approach will be considered by one of the Task Group members

whose company is experienced in this general technique. Based upon the conclusion of the laboratory, the question of further work on this procedure should be considered.

When the results of these screening experiments are available, it should then be possible to develop a plan for incorporating known quantities of VCM into the diets of rats. This may require daily preparation of the food and will almost certainly require frequent monitoring of the feed to provide a firm measure of the actual concentration in the animal's diet. When this has been done, a full protocol for a feeding study can then be submitted to the Food and Drug Administration for its views, following which the study could be initiated.

In previous conferences, the Food and Drug Administration has indicated that the results of a 90-day feeding study should be submitted to supplement the "no migration" position set forth in the Comments filed by SPI. However, in light of the implication of possible carcinogenesis, this Committee feels that lifetime feeding studies will be required to provide long-term insurance against "future shock". For this reason we believe that the required 90-day feeding study should be supplemented by a lifetime feeding study, often called a two year feeding study.

We estimate that a 90-day feeding study would require approximately $75,000 allocated as follows:

WORK	MONEY	TIME TO COMPLETE
Feasibility and biological availability	$25,000	3 months
90-day Rat Study	$40,000	6 months
Contingency	$10,000	------
TOTAL	$75,000	9 months

The $40,000 allocated to the 90-day rat study is significantly higher than is generally encountered in an ordinary feeding study. However, this figure is suggested because of the very strong likelihood that extensive and frequent analytical work will be required, as well as daily preparation of feed for the animals.

A two-year feeding study of the type envisioned by the Task Group is estimated to cost approximately $150,000 allocated as follows:

WORK	MONEY	TIME TO COMPLETE
Feasibility	$25,000	3 months
Lifetime feeding study	$100,000	33 months
Contingency	$25,000	-------
TOTAL	$150,000	36 months

The feasibility study would be the same as that required for the 90-day study. The estimated cost of $100,000 includes the consideration that frequent make-up of feed and extensive analytical monitoring will be required.

It is possible to combine the 90-day feeding study with a two-year study by including the animals needed for the 90-day study (which will be fed at a higher dietary level) along with the animals used for the two-year study. It is estimated that the cost for such a tandem study will be approximately $170,000, that is, more than the two-year study alone, but somewhat less than the two studies conducted one after the other. Furthermore, by this tandem arrangement both the 90-day study and the two-year study will be available in the total elapsed time of three years, whereas if they were conducted sequentially the final results would not be available for approximately 3 3/4 years. In either case, however, the 90-day study would be available at the same time.

The Task Group recommends that this work be assigned to Food and Drug Research Laboratories, (FDRL), 60 Evergr en Place, East Orange, New Jersey. The full details of a protocol for the feeding study will be prepared by FDRL before February 15. It is expected that FDRL will also prepare a critique of the Viola paper pointing out that the study, as conducted, is not scientifically appropriate as a means of evaluating the oral toxicology of VCM.

This Task Group would like to point out that an appropriately selected Committee should make appropriat arrangements to monitor this work since it is the opinion of the Task Group that this function is outside its scope.

Turning to other points raised by the Food and Drug Administration during its conference on December 20, the Task Group recommends that the Ad Hoc Liquor Bottle Committee

recommend that vari us resin suppliers and bottle manufacturers begin long range studies at 72°F with water, dilute acetic acid, 8% ethanol, 50% ethanol and edible oil. These various solvents should be stored in bottles made from "new" compounds of known residual VCM levels and should be analyzed periodically for at least nine months. In addition, efforts should be made to obtain samples of food such as vinegar, edible oil, and peanut butter presently packaged in "old" compounds and available in stores throughout the country. The food should be analyzed for VCM content as requested by the Food and Drug Administration.

With respect to the questions raised regarding the referee procedures, Continental Can Co. and M & T Chemical Co. will be conferring in due course with the Food and Drug Administration Staff to resolve the questions.

With the presentation of this report this Task Group feels it has now discharged its responsibility to the Ad Hoc Liquor Bottle Committee.

Respectfully Submitted,

Arthur Sheldon

Arthur Sheldon

MEMBERS OF TASK FORCE

Continental Can Company
633 Third Avenue
New York, New York 10017
John E. Farrell

Continental Can Company
7622 S. Racine Avenue
Chicago, Illinois 60620
Charles J. Spiegl

Ethyl Corporation
451 Florida Avenue
Baton Rouge, La. 70801
William E. Rinehart

Food & Drug Res. Labs
Waverly, New York
K. Morgareidge

Keller and Heckman
1150 17th Street, N. W.
Washington, D. C. 20036
Jerome H. Heckman
D. S. Dixler

M & T Chemicals Inc.
P. O. Box 1104
Rahway, New Jersey 07065
A. W. Sheldon

Stauffer Chemical Co.
Westport, Ct. 06880
A. B. Lindquist

Society of the Plastics Industry, Inc.
250 Park Avenue
New York, New York 10017
Thomas J. McGrath