



INTERNAL CORRESPONDENCE

CHEMICALS AND PLASTICS

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To (Name) Dr. W. B. Ackart, 312 Date March 28, 1977
Division Mr. H. M. Bartlett, 701-125
Location Dr. T. K. Brotherton, 701-324 Originating Dept. Research and Development
Copy to Mr. C. H. Carder, 720-34 Subject Vinylidene Chloride Toxicity
Mr. K. D. Cavender, 720-132B
Mr. F. DeRosa, 707-202
Mr. R. J. Hanna, 720-129
Mr. J. R. Hazle, Tucker
Mr. J. B. Johnson, 770-306
Dr. J. E. Johnston, 720-128
Mr. K. G. Morlock, Alsip
Mr. W. I. Wertz, 312
Dr. F. G. Willeboordse, 312
Mr. R. T. Wood, 706-206

cc: Mr. R. W. Annonio, NYO-33
Dr. D. L. MacPeck, 701-246
Mr. J. J. Smith, 740-4422
Mr. W. E. Whitehurst, 701-247

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DO NO REMOVE

Gentlemen:

Attached is a letter from PPG which updates the studies on vinylidene chloride monomer (VDCM) toxicity. PPG continues their recommendation that concentrations of VDCM in the work area be maintained below 10 ppm at all times. They also recommend that the eight-hour time-weighted average (TWA) concentration be maintained as far below 10 ppm as practical.

Mr. MacMillan's letter states that this information should be passed on to our customers. UCAR Vehicles 4590X, 4591X and 4592X are currently being evaluated by our customers in can interior topcoat applications. The latest results that I have seen on residual VDCM levels in three samples of 4590X are 5.4, 7.1 and 1.3 ppm. Based on all of this information, I am requesting an opinion from Mr. J. B. Johnson and Dr. W. B. Ackart on whether the information from PPG should be sent to these customers.

Very truly yours,

T. L. Dawson

TLD:noh

Enclosures

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R. N. WHEELER, JR.

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PPG INDUSTRIES, INC./ONE GATEWAY CENTER/PITTSBURGH, PENNSYLVANIA 15222/AREA 412/434-2515

JOHN L. MacMILLAN
Vice President, Sales and Distribution
Industrial Chemical Department
Chemical Division

RECEIVED
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TLD

March 18, 1977

Dr. Tom Dawson
Union Carbide
Chemicals & Plastics
P. O. Box 8361
South Charleston, West Virginia 25303

Dear Dr. Dawson:

In January, 1977, I wrote you concerning vinylidene chloride monomer (VDCM). In my letter, I mentioned a letter dated January 17, 1977 from the Manufacturing Chemists Association (MCA) which informed PPG of new preliminary information developed independently by the European Study Group for Vinylidene Chloride Toxicity. The information that PPG received was not detailed; however, it was reported that some of the test (Swiss) mice exposed to VDCM developed kidney tumors while test rats and hamsters did not. The European Study Group further announced that Professor Cesare M. Maltoni, the Study Group's principal investigator, would present his preliminary findings at the Technical Association of the Paper and Pulp Industry (TAPPI) meeting in Hamburg, Germany, on January 26, 1977.

Since being notified of Maltoni's preliminary findings, an attempt has been made to obtain additional details. Professor Maltoni did not provide a formal written report of his findings at the Hamburg meeting; therefore, information thus far obtained by PPG is subject to further confirmation and verification.

Our current information is that Professor Maltoni exposed (via inhalation) groups of 30 mice of each sex to 1, 10, 25, and 50 ppm for four hours per day, five days per week. At 50 ppm, the mice had a high mortality incidence. Therefore, a second group of 120 mice per sex was then started on exposure to 25 ppm. Hamsters were exposed to 25 ppm, while groups of rats were exposed to 0, 10, 25, 50, 100 and 150 ppm

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VDCM. At the 82nd week, there were no kidney tumors reported in the hamsters or the test rats. Male mice exposed to 25 ppm were reported to have a kidney tumor incidence of approximately 10 per cent, while only one female mouse was similarly affected. The tumors in the male mice were unilateral (one kidney) while the one female kidney tumor was bilateral (affecting both kidneys). The mice exposed to 10 ppm were not reported to have kidney tumors in either sex.

Professor Maltoni also had placed on test, rats that were receiving VDCM by oral gavage. Dosage levels ranged as high as 20 mg/kg/day. After 24 months of dosing, there were no reported increased incidence of kidney tumors.

The preliminary verbal report by Professor Maltoni should be put in proper perspective. The exposure level used for mice was near the lethal level, was toxic to the kidney, and was administered to a strain of mice that is inherently susceptible to a high incidence of spontaneous kidney disease. Professor Maltoni recognized that further research should be undertaken using another mouse strain that has a low incidence of kidney disease.

On February 22, PPG learned that Professor Maltoni had also given his preliminary VDCM report at a meeting held in New York City. Dr. C. Hammond, officer for the American Cancer Society, called a press conference where this information was released.

On February 23, 1977, The Wall Street Journal, The New York Daily News and The New York Times carried the story and I am enclosing copies of these articles.

In further developments, PPG has received a tentative agenda of a conference on Comparative Metabolism and Toxicity of Vinyl Chloride and Related Compounds to be held in Bethesda, Maryland on May 2-4, 1977. This Conference is being conducted by the National Institute of Environmental Health and Safety (NIEHS). Both Professor Maltoni and P. L. Viola are on the tentative agenda. Since VDCM is to be one of the chemicals discussed, PPG contacted the NIEHS Associate Director, Dr. Hans Falk, to suggest that the MCA VDCM industry-sponsored toxicity research also be included on the conference agenda. We are optimistic that NIEHS will favorably consider the industry request.

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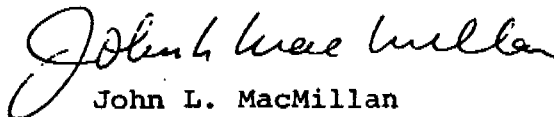
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In summary, PPG does not have any evidence that VDCM has produced cancer in humans or any animal species except Swiss mice. VDCM has been reported to have minimal toxic effects to the liver of rats at 25 ppm in the MCA study.

PPG continues our recommendation that concentrations of VDCM in the work area be maintained below 10 ppm at all times. It is also recommended that the eight-hour time-weighted average (TWA) concentration be maintained as far below 10 ppm as practical. As more information becomes available to PPG, we will continue to keep you advised.

The above information should be passed on to your employees and customers.

Yours very truly,



John L. MacMillan

/kf

Attachments

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Study Says Chemical Used in Food Wrap Gave Mice Tumors

Findings by Italian Scientists
Raise Concern Over Effect
Of Substance on Humans

By GAIL BRONSON

Staff Reporter of THE WALL STREET JOURNAL

NEW YORK — Italian scientists have found that vinylidene chloride, used in plastic packagings of food, causes kidney cancer in certain strains of mice. The initial study results arouse concern that the chemical may possibly cause human cancer.

Vinylidene chloride is a chemical used in combination to make many plastic wraps and plastic containers used largely in food packaging. The chemical is molecularly related to vinyl chloride, used in various household plastic products, which was determined to cause human liver cancer four years ago.

The study, conducted at the University of Bologna by Dr. Cesare M. Maltoni, found that 20% of 120 male mice subjected to lifetime inhalation of vinylidene chloride, at 25 ppm (parts per one million parts of air), developed kidney cancer. In higher doses the animals died before they could develop cancer, said E. Cuyler Hammond, an American Cancer Society officer who presented Dr. Maltoni's study at a news conference.

No Federal Standard

Although no federal standard exists for the chemical, an unofficial organization of industrial hygienists recommends maximum work exposures of 10 ppm.

Dr. Maltoni's study also subjected mice to inhalation of the chemical at 10 ppm for two years and they suffered no ill effects. In studies of Chinese hamsters and rats, exposure to vinylidene chloride causes no ill effects. Dr. Maltoni is testing other strains of mice and hamsters.

Despite these scant findings, both the federal government and private industry are assiduously studying the possible cancerous effects of the chemical because of its similarity to vinyl chloride. Dr. Maltoni's results are considered significant by some because "he induced a cancer in mice which is rarely formed spontaneously," says Dr. John F. Finklea, director of the National Institute of Occupational Safety and Health.

Nationwide Mortality Study

The institute began a nationwide mortality study of workers exposed to vinylidene chloride last year. "We are alerting all industries and appropriate unions about Dr. Maltoni's data," says Roscoe M. Moore, the institute's chief of technical evaluation. "We are writing to all (company) medical directors to get any data they have on employees' liver or kidney disfunctions. Although the mice formed kidney tumors, we believe it may show up as liver cancer in humans."

Mr. Moore's opinion stems from an institute study of a BASF Wyandotte Corp. plant in South Kearny, N.J. The company was alarmed at the results of a 1973 screening of liver functions it had done on 46 employees it knew to have been exposed to vinylidene chloride in the past. Last February workers requested the institute to study the situation further. NIOSH official Bobby Craft said hygienists found "moderate liver changes (among workers) but we don't know the significance yet."

Hygienists examined 235 workers at the plant, which no longer produces vinylidene chloride. The institute plans to do a mortality study of plant workers in the next few months.

BASF Wyandotte is a division of BASF AG, the West German company that sponsored Dr. Maltoni's work. Dow Chemical Corp.'s Europe division, Imperial Chemical Industries of Great Britain, and Solvay of Belgium also contributed funds to the research along with the Italian government.

Record of Employees

Dow Chemical is the largest domestic producer and user of vinylidene chloride, primarily in its plastic Saran Wrap. Dow said it has records of 138 workers since 1944 who have been exposed to the chemical, at anywhere from 10 ppm to 70 ppm. The company hasn't found any visible ill effects among this group. Dow said worker exposure in its Freeport, Texas, plant, where the chemical is made, and in its Midland, Mich., plant, where Saran Wrap is made, is under one ppm.

Dow Chemical inhalation studies in rats in 20-ppm and 80-ppm doses didn't result in any tumor growths. A Dow spokesman said there was a "mild discernable effect on the liver" of rats given doses at 80 ppm. The company is conducting ingestion and reproduction studies in rats.

A major concern among health officials is transference of vinylidene chloride from plastic packaging to food. Dow Chemical said its Saran Wrap contains up to 10 ppm of the chemical but that it hasn't found any migration of vinylidene chloride to food when studied at the most minute levels.

The Food and Drug Administration said the agency is conducting studies to determine to what degree, if any, vinylidene chloride remains in plastic wrap after manufacture and if it transfers from the plastic to food.

PPG Industries Inc. in Pittsburgh is the second largest producer of vinylidene chloride. A spokesman said that in seven years it hasn't seen any health problems among its workers. Imperial Chemical, Solvay and BASF officials weren't immediately available for comment.

NEW YORK DAILY NEWS
February 23, 1977

Links Food Wrap Chemical to Cancer

By HUGH WYATT

A chemical used in the manufacture of certain plastics, including some clear plastic food wraps, has been found to cause kidney cancer in male mice, new findings by an Italian research scientist revealed yesterday.

The chemical, known as vinylidene chloride, is related to vinyl chloride, which already has been proved to have cancer-causing properties under certain circumstances.

But it is not known whether vinylidene chloride poses "any danger of any

kind" to humans, a Mount Sinai Medical Center scientist said.

The research was done by Dr. Cesare Maltoni, the director of the Institute of Oncology and Tumor Center at the University of Bologna in Italy. He said his conclusions were based on two years of studying the effect of the chemical on mice, hamsters and rats.

During this period, some of the animals were fed the chemical through stomach tubes and others were made to inhale it in gaseous form, he said. Only the male mice developed kidney cancer.

Maltoni made his findings known at the New York Academy of Science, at 2 E. 63d St. Two Americans, Dr. E. Cuy-

ler Hammond, the chief epidemiologist of the American Cancer Society, and Dr. Irving Selikoff, the director of Environmental Sciences and Laboratories at the Mount Sinai Medical Center, interpreted most of Maltoni's findings. The visitor spoke mainly in Italian.

Asked about the possible effects the chemical would have on humans, Selikoff said, "It is not known whether any danger of any kind exists. This information is new and we have no (other) information."

The Food and Drug Administration said it was studying Maltoni's findings and would issue a report later.

Cancer Experts Warn of Dangers In Some Plastic Wrap Chemicals

By JANE E. BRODY

The finding by a leading Italian researcher that a chemical used in some plastic food wraps can cause cancer in mice prompted two American cancer experts yesterday to alert the public and Government agencies to the need for closer scrutiny of this and related chemicals.

At a news conference at the New York Academy of Sciences, Dr. E. Cuyler Hammond and Dr. Irving J. Selikoff said that the chemical, called vinylidene chloride, was closely related to two other cancer-causing chemicals, vinyl chloride and trichloroethylene.

However, researchers at the Dow Chemical Company, the leading manufacturer of vinylidene chloride, said the Italian finding was of questionable significance and cited a two-year, \$1 million study sponsored by American industries that showed no cancer-inducing effect of vinylidene chloride in rats.

In addition, Dow researchers said that studies of foods wrapped in plastics made from vinylidene chloride had showed that none of the chemical migrated from the wrapping to the food. The test would have disclosed such contamination if it exceeded 10 parts of vinylidene chloride in one billion parts of food.

In the Italian study, conducted by Dr. Cesare Maltoni at the Institute of Oncology in Bologna, rats, hamsters and mice were exposed to vinylidene chloride gas at much higher levels—starting at 10 parts per million—for up to one year. Kidney cancers developed in about 20 percent of the male Swiss mice, but in none of the other animals.

Three years ago, Dr. Maltoni's studies of vinyl chloride, another plastics chemical, showed it to cause cancer in rats and mice. Shortly afterward the chemical was pinpointed as the cause of a rare, fatal liver cancer in exposed workers. Dr. Maltoni's studies of vinylidene chloride were begun at the behest of four European producers.

Vinylidene chloride is a gaseous chemical that, when polymerized with vinyl chloride, makes up Saran Wrap, a Dow product. (Other packaged plastic wraps are made of polyethylene.) The vinylidene chloride-vinyl chloride copolymer—called saran—is also used to wrap commercially prepared meats and cheeses. A Dow spokesman said that about one-third of the flexible plastic packaging for food in grocery stores is saran, representing an annual market of between 150 and 200 million pounds of plastic.

In announcing their concern about Dr.

Maltoni's findings, Dr. Hammond, a vice president of the American Cancer Society, and Dr. Selikoff, director of environmental medicine at Mount Sinai Medical Center, said they saw no reason for the public to stop using saran products. But Dr. Hammond suggested that industry might try to remove residual vinylidene chloride from the finished plastic before it came into contact with food.

They said that Dr. Maltoni's finding warranted further examination by the Food and Drug Administration, the National Institute of Occupational Safety and Health and the National Institute of Environmental Health Sciences.

In a related development, the Natural Resources Defense Council has asked the Food and Drug Administration to recall existing stocks of Coca Cola in plastic bottles made from acrylonitrile, also called vinyl cyanide and another chemical relative of vinyl chloride. In response to a suit brought by the council in 1975, the drug agency last Friday rescinded its approval of market tests of the plastic soda bottles.

The agency's decision was based on recent findings that acrylonitrile causes birth defects and tumors in test animals and that small amounts of the chemical leach out of the bottles into the drink.

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