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CHEMICAL MANUFACTURERS ASSOCIATION

July 8, 1992

To: Ethylene Dichloride Panel Members

Re: Follow-Up Items from June 29th Conference Call

There were several issues raised during the June 29th EDC Panel conference call which I agreed to address. Below is a list of those issues and the actions which I have taken:

Determination of the Status of EDC in EPA's RM process

I called Linda Moos at EPA regarding EDC's inclusion in the risk management process. She told me that EDC is in RM2. I explained that the Panel companies have not received any official notification that EDC had progressed to RM2. She thought letters had gone out, but admitted that the move to RM2 happened so long ago and EPA may not have been sending notification letters at that time. I told her that the Panel has expressed concern with the RM1 findings and would like an opportunity to meet with the Agency if possible.

At this time, EPA is waiting for feedback from their regional offices and will then move forward with a public review of the findings, including a stakeholders meeting. It is unlikely that the meeting will occur this summer, as was one time anticipated. Ms. Moos felt that the stakeholders meeting would be the best time for the Panel to address some of its concerns, rather than a separate meeting. She noted that EPA is primarily concerned with occupation and public exposure, and not any particular use of EDC. She also said that the Agency is looking at EDC releases.

I intend to get a copy of EPA's administrative record on EDC, which I will forward to all Panel members. I will also periodically check with EPA to determine if EDC's status has changed.

Epidemiology Study

During the June 29th conference call, there was some discussion about a Union Carbide epidemiology study conducted in a West Virginia facility. I contacted the study researcher, Dr. Jane Teta, who told me that the study has been submitted to a journal and that she expects a published report to be available within the next three months. In the meantime, she does not want to give me copies of the draft for circulation within the Panel.

2501 M Street, NW, Washington, DC 20037 202-887-1100 Panafax 202-887-1237 Telex 89617 (CMA WSH)

SL 063878

Study Submitted by Shell under CAP Program

You may recall that I provided copies of a letter from Shell which submitted a teratology study under the CAP program. There was some questions as to whether the teratology study was an EDC Panel study or not. I found the original report, and it was sponsored by the EDC group. A copy of the study title page and study summary are attached for your reference. If you should need a copy of this report, please feel free to call me.

Ohio Right to Know Initiative

Attached for your information is a guideline on how the Ohio initiative is expected to work in practice.

I believe these were all the action items raised during the June 29th conference call. If you have any questions regarding this memorandum, please call me at 202-887-1146. Thank you.

Regards,

Kathleen M. Roberts
Manager
Ethylene Dichloride Panel

SL 063879

The Effects of Inhaled Ethylene Dichloride on Embryonal and Fetal Development in Rats and Rabbits

BY:

M. M. Schlachter, A. A. Crawford, J. A. John, T.S. Lederer, F. J. Murray, J. S. Murray, and M. K. Pilny

Reviewed By:

K. S. Rao

Toxicology Research Laboratory
Health and Environmental Science, USA
Dow Chemical U.S.A.
Midland, Michigan 48640

January 23, 1979

This study was supported by companies sponsoring research on ethylene dichloride and was administered by the Manufacturing Chemist's Association.

SL 063880

The Effects of Inhaled Ethylene Dichloride on Embryonal and Fetal Development in Rats and Rabbits

By: M. M. Schlachter, A. A. Crawford, J. A. John, T. S. Lederer, F. J. Murray, J. S. Murray and M. K. Pilny

SUMMARY

Pregnant Sprague-Dawley rats and New Zealand White rabbits were exposed to 0, 100 or 300 ppm of ethylene dichloride for 7 hrs/day on days 6 through 15 (rats) and 6 through 18 (rabbits) of gestation. Severe maternal toxicity was observed among rats exposed to 300 ppm of ethylene dichloride; two-thirds of the animals died during the exposure period. No signs of toxicity were observed among rats at the 100 ppm dose level. Maternal toxicity was noted in rabbits as evidenced by maternal deaths at both dose levels. No adverse effects on embryonal or fetal development were observed among litters from the exposed rats at 100 ppm or among those from exposed rabbits. Due to the severe maternal toxicity observed, no conclusions would be drawn concerning the teratogenic potential of inhaled ethylene dichloride in the rat at 300 ppm; ethylene dichloride was not embryotoxic or teratogenic in rats inhaling 100 ppm or in rabbits inhaling 100 or 300 ppm of the compound during gestation.

SL 063881

Shell Oil Company

One Shell Plaza
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Houston, Texas 77252

Roy D. Gerard
Vice President
Health, Safety & Environment

November 22, 1991

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
ATTN: 8(e) Coordinator (CAP Agreement)

Dear Sir:

SUBJECT: INFORMATION SUBMITTED UNDER THE COMPLIANCE AUDIT PROGRAM PURSUANT TO THE TERMS OF AGREEMENT BETWEEN SHELL OIL COMPANY AND THE ENVIRONMENTAL PROTECTION AGENCY.

IDENTIFICATION NUMBER: 8ECAP-0050

REFERENCE: SHELLCAP-64

The enclosed information was found in an audit being conducted within Shell Oil Company under the Terms of Agreement of EPA's Compliance Audit Program. It is being submitted pursuant to the TSCA 8(e) Compliance Audit Program and the EPA-Shell CAP Agreement (ID. No. 8ECAP-0050).

The enclosed information is from a developmental toxicity study in rats and rabbits conducted on ethylene dichloride. The results were reported as HSE-79-0195 (00393) The Effects of Inhaled Ethylene Dichloride on Embryonal and Fetal Development in Rats and Rabbits.

The associated chemical substance is:

1,2-Dichloroethane, CAS No.107-06-2

It is also called: Ethylene dichloride.

The enclosed information indicates that: Ethylene dichloride caused complete embryotoxicity (no live births occurred) at the highest dose tested, 300 ppm, in rats. This dose also caused severe

SL 063882

For Distribution by CMA
CHEMSTAR DIVISION

From E. Festa Watson
Ref. No. re All PMs
Date 7/2/92

HOW WILL THE O.C.A. INITIATIVE PLANT NOTIFICATION REQUIREMENT WORK IN PRACTICE?

Step 1. Gather the lists that apply. The list directly contained in the Initiative has 500-plus chemicals; these are California listings made by a California science panel. Then add to those chemicals also the additional lists that must be included within 1 year after the effective date, including the lists of carcinogens done by the FDA, EPA, National Toxicology Program, National Institute of Occupational Safety & Health (all government agencies) and the International Agency for Research in Cancer of Lyon, France (an international group). If you don't have these lists hire a chemical toxicology consultant or ask Ohio EPA for them.

Step 2. Check the ingredients of your containers of products that (1) have come into the plant from outside, or (2) are distributed by you in Ohio. Do the containers already say, "WARNING: THIS PRODUCT CONTAINS A CHEMICAL KNOWN TO CAUSE CANCER, BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM" ? If they do not have this warning, it may mean that you do not knowingly have among the ingredients one or more chemicals that are on these lists. Or if the container does have one of these ingredients (check label, material safety data sheet, specifications, catalogues, etc.), then if you do not place warnings, you must determine, subject to challenge, that the amount of the chemical when compared to exposures will not either exc ed the threshold of one marginal additional cancer in one milli n persons exposed over a lifetime (this is ten times more stringent than California) or the threshold of 1/1,000 of the no effect l vel (NOEL) for reproductive harm. (We recommend that an experienced toxicologist do this evaluation for you.)

Step 3. Now that you know which materials require warnings, consider the exposure to the community around your facility. With input from a consultant, just as in Step 2, make the 1 in 1,000,000 additional cancer case, and the 1/1,000 NOEL calculation for the facility's releases or exposures to persons outside the facility. If you do not warn the people working and living around the facility then you assume the responsibility to prove the levels f risk are below these thresholds of warning, and you assume the risk of potential penalties.

Step 4. Next -- if you decide that any one of the chemicals in the facility exceeds the threshold for notification, then you mail, every six months, a letter to each person who lives or works within 2 miles of the facility. The letter states your name and address, the chemicals that you have that are listed and are above th threshold, and states WARNING: THIS AREA CONTAINS CHEMICALS KNOWN TO CAUSE CANCER, BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM. B cause you only avoid liability if you prove notice was given, you should

spend the $2.29 per letter t send via certifi d mail, return r ceipt requ sted. Do n t include language diminishing the risk unless you are prepared t defend a charge of inadequate warning.

Step 5. The letters are received. Any person who works or lives within the 2-mile radius can send a complaint to Ohio EPA (signed before a notary) that alleges (need not prove) the person did not get an adequate notice of all your chemicals.

Step 6. As soon as the complaint is received, Ohio EPA must send you an order compelling you to conduct an inventory.

Step 7. The inventory must be done of all of the facility's chemicals that are on the list (and subsequent lists, when they are in effect) for the preceding calendar year, e.g. a request n 6/1/95 will be for calendar 1994 chemical inventories. Those who d Form R SARA 313 reports already have a system in place and can expand it. Utilities, warehouses, food and drug establishments, etc., must set up a system like the inventory of SARA 313 materials in order to be able to quickly prepare these inventories. One inventory per year per facility is the requirement; you can be tapped by the same group of requesters once each year via a new complaint to Ohio EPA.

Step 8. The inventory form goes to Ohio EPA. A simply mathematical decision is made, comparing your totals to the RQ lists. Th RQ lists are several US EPA listings of chemicals, about 1,030 in all, which if released above a "reportable quantity" will trigger a duty to report to US EPA. These lists are not the same as the inventory lists and it is not clear why these other lists were used. Th comparison is made by Ohio EPA.

Step 9. If the amount in the inventory is ten times the RQ for any chemical on the list, then there must be an exposure assessm nt document prepared. The cost of this will be at least $200,000 f r the medium size manufacturing facility, according to a national expert on risk assessment methodology. It must be done within 6 months unless Ohio EPA allows an extension. Nine questions spelled out in the law must be answered. These will include extremely complex cancer and health calculations, exposure calculati ns, assumptions, fugitive emissions, etc. The very detailed analysis done by the expert technical consultants will produce a very large document, the exposure assessment for each of the chemicals in y ur facility that are listed. One exposure assessment may be required of each facility each year. Avoid mistakes in these assessments as a charge of false official statements may be made along with the penalties described below.

Step 10. The exposure assessment is then mailed to Ohio EPA. Under the "gag rule" Ohio EPA is forbidden to comment upon the contents and conclusions of this assessment (we don't know why).

Step 11. Ohio EPA must adv rtise in the local newspaper that your exposure assessment is available and it must print a copy for the local library. Ohio EPA will send a copy to the person who first filed the complaint.

Step 12. If you failed to do any of the above steps and you acted with careless disregard of the consequences for the persons who should have received a warning, then you can be indicted for the felony of criminal failure to warn. Upon conviction, you would be barred from state contracts, barred from voting as a convicted felon, and subject to appropriate jail terms and fines.

Step 13. If you failed to do any of the above steps and used good faith and did not act recklessly, your penalty is a civil penalty. Ohio EPA or the local health board may order the local prosecut r (who has no discretion to refuse) to start a penalty case. Or, the citizen group may give notice that it intends to start a penalty case unless the public officials act.

Step 14. Between the date when the listing became effective or the date the chemical appeared on your property, whichever is later, and the subsequent date when the jury verdict in your civil case (step 14) is reached, you can be fined up to $2,500 per day or a total of $912,500 per year. The warning cases have a clock that ticks at more than $100 per hour, pressuring the companies to settle by paying the challenger a lesser amount and agreeing to warn of the exposure. For example, lead crystal decanters as wedding gifts contain lead; groups in California that sued th Waterford crystal sellers got a settlement of $600,000.

Step 15. By delivering the exposure assessment document to the complainant, you have made admissions against interest that can be used in a toxic torts case against you for those who allege injury was caused by exposure from your facility.

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