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~~DLH~~ 2. REB

D. L. HEYWOOD

What do you think we should do about this? How do other cos. deal with such requests?

How do we get points for being "nice guys"? REB

Dave Liebeskind

As promised

MGO

Union Carbide C
Community & Em
& Environmen

39 Old Ridgebury Road
Danbury, CT 06817-0001

12/11/86

er 21, 1986 REB:

TO: R. C. Wi
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CC: W. E. Cham
N. W. Gaines
H. L. Greenberg
D. L. Heywood
E. K. Jensen
M. G. Ott

SUBJECT: Vinyl Chloride Epidemiology Study

Dear Dick:

Attached is a copy of the EPA response to our "FYI" submission n September 9, 1986 concerning the CMA-sponsored epidemiology study f vinyl chloride workers. Please note the second paragraph of page 1 of the EPA October 14, 1986 letter:

> "In view of EPA's general interest in Corporate actions that are taken on a voluntary basis in response to chemical toxicity or exposure information. EPA requests that you describe the actions that Union Carbide Corporation has taken or plans to take to notify workers and others about the epidemiologic findings cited in the above referenced TSCA Section 8(e) submission."

Would you please prepare an appropriate response to this inquiry s that we can respond in a timely manner. Thanks.

Very truly yours,

Bill

W. C. Kuryla
Secretary, SREB

WCK:rl
Attachment

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UCC
004863

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 14 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

Mr. Cornelius C. Smith, Jr.
Vice President
Community and Employee Health, Safety
and Environmental Protection
Union Carbide Corporation
39 Old Ridgebury Road
Danbury, CT 06817-0001

Dear Sir:

With regard to:

TSCA Section 8(e) submission on: Vinyl Chloride

Submitted by: Union Carbide Corporation

Date submitted: September 9, 1986

EPA Document Control Number: 8EHQ-0986-0629

EPA's Office of Pesticides and Toxic Substances has completed a preliminary evaluation of the above referenced submission under Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA). The enclosed status report is the result of that preliminary evaluation but does not, however, necessarily represent EPA's final conclusion on vinyl chloride.

In view of EPA's general interest in corporate actions that are taken on a voluntary basis in response to chemical toxicity r exposure information, EPA requests that you describe the actions that the Union Carbide Corporation has taken or plans to take t notify workers and others about the epidemiologic findings cited in the above referenced TSCA Section 8(e) submission.

RECEIVED
OCT 21 1986
W. C. KURYLA

REC
OCT 20 1986
W. E.

UCC
004864

In responding to this request for information, or in therwise communicating with EPA regarding this submission under Section 8(e), please refer to the EPA Document Control Number that has been assigned to the submission. As in the case of initial 8(e) submissions, all responses/correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110; March 16, 1978).

Any confidentiality claims should be supported by submission of information as described in the enclosed item entitled "Support Information for Confidentiality Claims." All available information requested by this letter should be transmitted to the EPA Document Control Officer at the address below within 20 working days of your receipt of this letter; any requested information or supplemental information that becomes available following your response to this EPA letter should be transmitted to the Agency immediately upon your company's receipt of such information.

Document Control Officer (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Should you have any questions or comments prior to responding to the Agency's request for additional information, please contact Mr. David R. Williams of the Chemical Screening Branch/ECAD at (202)-382-3468.

The Environmental Protection Agency looks forward to continu d cooperation with the Union Carbide Corporation in its ongoing efforts to evaluate and minimize the potential risks posed by chemical substances to health or the environment.

Sincerely,

Frank D. Kover

Frank D. Kover, Chief
Chemical Screening Branch
CSB/ECAD/OTS/OPTS (TS-778)

Enclosures

DATE: OCT 14 1986

SUBJECT: Status Report* 8EHQ-0986-0629 Approved: 10/14/86

FROM: James F. Darr, Section Head
Chemical Risk Identification Section/CSB

TO: Frank D. Kover, Branch Chief
Chemical Screening Branch/ECAD/OTS/OPTS

Submission Description

The Union Carbide Corporation submitted a copy of draft final report entitled "Epidemiologic Study of Vinyl Chloride Workers." (According to Union Carbide, the study had been conducted for the Chemical Manufacturers Association (CMA).) The "Summary" section of the submitted report presented the following information with regard to the conduct and results of the performed epidemiologic study:

> "The cohort consisted of 10,173 men who had worked for at least one year in jobs involving exposure to vinyl chloride prior to January 1, 1973. These men were employed at 37 plants in the U.S. belonging to 17 companies. Observation of the mortality experience of the cohort was extended to December 31, 1982. A total of 1536 cohort members were identified to have died. The observed mortality, by cause, was compared with the expected based on U.S. mortality rates, standardized for age, race and calendar time. Analyses by length of exposure, latency, age at first exposure, calendar year of first exposure and type of products were performed. The [performed epidemiologic] study confirmed that the vinyl chloride workers [had] experienced significant mortality excesses in angiosarcoma (15 deaths), cancer of the liver and biliary tract (SMR = 641), and cancer of the brain and other central nervous system (SMR = 180). In addition, the study also found a significant mortality excess in emphysema (SMR = 179). On the other hand, the study did not find any excess in either respiratory cancer or lymphatic and hematopoietic cancer."

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* NOTE: This status report is the result of a preliminary evaluation of information submitted to EPA pursuant to Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA). The statements made in this report should not be regarded as expressing final EPA policy or intent with respect to the subject chemical(s). Any review of this status report should take into account the fact that the report may be based on incomplete information.

In submitting this report to EPA, Union Carbide stated that "the information on excess emphysema observed in [the] vinyl chloride workers is not reliably ascribed in the report to exposure to vinyl chloride because of: (1) potential problems involved in th cause of death coding for emphysema; (2) the manner in which the diagnosis of emphysema was made (clinically or pathologically; (3) the possible contribution of other factors such as smoking and geographical variation; and (4) the absence of precedents in experimental animals." In addition, Union Carbide stated that the apparent excess of biliary tract cancer "may be explained by failure to diagnose angiosarcoma properly."

Submission Evaluation

The submitted epidemiological study continued the follow-up of 10,173 workers who were exposed to vinyl chloride for 1 year or more between 1942 (or on initiation of complete recordkeeping systems at the studied plant) and December 31, 1972. The vital status of 9200 members was characterized as of December 31, 1982. Within the period of the study, 1536 (16.7% of the cohort) died. When compared to the mortality experience of U.S. white males, this cohort had a statistically significant deficit in total mortality. Statistically significant increases in mortality were observed from neoplasms of the liver and biliary tract (Standard Mortality Ratio (SMR)=641.2; $p<0.001$; 37 observed), brain and central nervous system (SMR=180.2; $p<0.05$; 23 observed) as well as emphysema (SMR=179.6; $p<0.01$; 41 observed).

The excesses in liver and brain cancers have been reported in other epidemiological studies of vinyl chloride-exposed workers, while the excess in emphysema deaths appears to be the first of its kind. Liver cancers and angiosarcomas have been causally linked to vinyl chloride exposure and several studies have reported significant excesses in brain cancer mortality. In this TSCA Section 8(e) submission, the liver and biliary cancer SMR's showed a highly significant increasing trend in analyses with increasing length of exposure and with increasing latency since first exposure. These trends appear also in the the analyses f the brain cancer deaths. By contrast, analyses of the emphysema deaths showed a decreasing trend with length of exposure with the SMR being statistically significantly elevated for workers with exposures of less than 10 years. The excess in emphysema deaths was limited to polyvinyl chloride manufacturing and to workers who were 35+ years of age when first exposed. The observed emphysema excess was not associated with the year of first exposure or with latency since first exposure.

The limitations of the reported study include the lack of control for confounding exposure such as smoking or other occupational agents. In addition, bias may have been introduced because the deaths were not histologically confirmed. It should be noted, however, that these particular limitations (and others listed by Union Carbide) are insufficient to explain the observed excess in emphysema deaths.

In conclusion, this epid miological study appears to have been conducted carefully and the results are presented in an unbiased fashion. The excesses in liver and brain cancers observed in the cohort could be used possibly to estimate low-level human cancer risks. The observed excess in emphysema deaths is a finding that deserves further attention. For example, an in-depth evaluation of the existing epidemiologic information on vinyl chloride could be conducted in order to determine the ability of previously performed studies to detect emphysema excesses.

Current Production and Use

A review of the production range (includes importation volumes) statistics for vinyl chloride (CAS No. 75-01-4), which is listed in the initial TSCA Chemical Substance Inventory, has shown that between 3.8 and 10 billion pounds of this chemical were reported as manufactured and/or imported in 1977. This production range information does not include any manufacturing/importation data claimed as TSCA Confidential Business Information (TSCA CBI) by the person(s) reporting for the initial TSCA Inventory, nor does it include any information that would compromise TSCA CBI. All information reported for the initial TSCA Inventory, including the production range information, is subject to the limitations that are contained in the TSCA Inventory Reporting Regulations (40 CFR 710).

According to Chemical & Engineering News (June 9, 1986 issue), U.S. production of vinyl chloride was 6.09 billion pounds and 7.78 billion pounds in 1984 and 1985, respectively.

According to secondary literature sources, applications of vinyl chloride include the chemical's use in the production of polyvinyl chloride, as a refrigerant, and as a plastics adhesive.

Comments/Recommendations

In its Section 8(e) submission, Union Carbide stated that any questions concerning the submitted report should be addressed to the Chemical Manufacturers Association.

It should be noted that the Office of Toxic Substances (OTS) has received several Section 8(e) and "For Your Information" (FYI) notices on vinyl chloride. It should be noted also that several EPA Program Offices (e.g., Office of Air and Radiation (OAR)) have evaluated or are currently evaluating available toxicologic and exposure data on vinyl chloride.

a) In view of EPA's general interest in corporate actions taken on a voluntary basis in response to toxicologic or exposure data, the Chemical Screening Branch (CSB/ECAD) will request Union Carbide to describe the actions the company has taken or plans to take to notify workers or others about the reported epidemiologic findings.

b) The Chemical Screening Branch will review the reported information in greater detail in order to determine the need for further OTS assessment of vinyl chloride.

c) The Chemical Screening Branch will send copies of this status report to OSHA, NIOSH, CPSC, FDA, NTP, OSWER/EPA, OW/EPA, OAR/EPA, ORD/EPA and OPP/OPTS/EPA. Copies of this report will be sent also to the TSCA Assistance Office (TAO/OTS) for further distribution.

SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS

The Environmental Pr tection Agency (EPA) has be n receiving many requests f r access to n tices submitted to EPA under Section 8(e) f TSCA. Accordingly, EPA must make a final confidentiality determination concerning the treatment of the information in your submission. In order to make that determination, EPA needs further information from you. Under EPA's regulations on the treatment of information claimed as confidential in 40 CFR Part 2 (41 FEDERAL REGISTER 36902, September 1, 1976), you have an opportunity to submit comments to substantiate your claim of confidentiality.

To comply with these requirements, you must indicate which portions of your submission are claimed as confidential. Be specific as to page, paragraph, or sentence as appropriate. For those portions that you identify as confidential, you must address the following questions. In answering the questions, be as specific as possible, give examples if necessary, and connect the specific answers to the specific claimed portions.

1. For how long a period do you desire confidential treatment? May EPA disclose this information after a certain date or after the occurrence of a specific event?

2. What measures have you taken to guard against undesired disclosure of this information to others?

3. To what extent have you disclosed this information to others, and what precautions have you taken in connection with the disclosures to protect against further disclosure?

4. Have there been any confidentiality determinations made by EPA, other federal agencies, or courts in connection with this information? If so, please enclose copies.

5. Do you assert that disclosure of this information would be likely to result in substanital harm to your competitive position? If so, what are those harmful effects, and why should they be regarded as substantial? What is the causal relationship between the disclosure and the harmful effects?

6. Do you assert that this information was voluntarily submitted as defined in 40 CFR 2.201(i)? If so, would the disclosure of this information tend to lessen the availability to the Government of similar information in the future? Why?

In making your claims of confidentiality and providing responses to the above questions, you should keep in mind that under section 14(b) of TSCA, "data from health and safety studies" are not entitled to confidential treatment, except to the extent that disclosure of such data would reveal either the portion of a mixture comprised of any of the chemical substances in the mixture or the processes used in manufacturing or processing a chemical substance or mixture. Any claim of confidentiality for data from health and safety studies that goes beyond these two types will be denied.