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Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: TSCA 8(e) Coordinator

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following information concerning an epidemiology study at Union Carbide's Bound Brook, NJ plant which the Agency may regard as being subject to TSCA § 8(e) reporting under its current guidelines. A nested case-control study was conducted to investigate whether an excess of pancreatic cancer, identified in a cohort mortality study, was associated with potential workplace exposures. The attached draft report (identified below) concludes that: "[o]ver the study period, significant exposure-related process changes occurred... Although PVC [polyvinyl chloride] and PE [polyethylene] processing operations could not be analyzed separately, the pancreatic cancer excess is more likely to be related to PVC processing, since this operation started earlier and involved more numerous potentially hazardous raw materials and exposures. Identification of a causative agent or combination of agents would require investigations with more detailed exposure information".

"Pancreatic Cancer Among Workers Processing Synthetic Resins", S.L. Selenskas, M. J. Teta, J. N. Vitale, Draft Business Confidential Report, Union Carbide Corp., July 23, 1993.

While no assertion of confidentiality is made, the Agency is advised that the publication rights to this information are the property of Union Carbide.

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 re CMT 7025.

Interoffice
 Communication

From:
 Date:

D. Penney
 September 16, 1993

Subject: Union Carbide report of Pancreatic Cancers in a PVC processing operation

I spoke with Dr. Jane Teta of Union Carbide about a report of an increased risk of pancreatic cancer in workers involved in PVC processing. Dr. Teta said that Carbide had recently reported the study to EPA, however, she was not willing to make a copy of the study available for wider distribution before it was accepted for publication. However, Dr. Teta offered to meet with the Vinyl Institute to discuss her findings. I told her that I would contact her if such a meeting was desired. Dr. Teta briefly summarized the study as follows.

Twenty-eight male pancreatic cancer cases which were compared to 140 control cases with no pancreatic tumors were included in the study. Workers were assigned to work areas where both PVC and polyethylene were processed. Men assigned for more than sixteen years to these areas experienced slightly over a seven-fold increased incidence of pancreatic cancer. No excess was seen amongst workers with shorter duration of assignments. Seven of the nine cases of pancreatic cancer began working in this area in the 1940s. All but three cases had worked 20 years or more.

While recognizing that the workers in this study were assigned to units in which both PVC and polyethylene were processed, Teta places most of the blame for the excess pancreatic tumor rate on the PVC processing. She believes this is because PVC processing practices of the time resulted in higher chemical exposures and involved working with more hazardous raw materials than polyethylene. Teta does not believe the increase of pancreatic tumors was due to vinyl chloride exposure. This is primarily because there were no cases of angiosarcoma of the liver. She instead points the finger at the phthalate plasticizers used in PVC, citing diethylhexyl phthalate being reported as carcinogenic in mice and rats. Teta also expressed concern for stabilizers, some of which contain cadmium and lead, which have been demonstrated to produce cancer in animals.

Teta maintains that chemical exposure of workers during PVC processing prior to the 1950s was very high because materials were weighed and fed manually into a blender. Workers climbed inside the blenders to scrape off excess chemical residues whenever different additives were required for different vinyl products. She says that this occurred

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as often as twice a day. Teta pointed out that the blenders that were used in polyethylene processing were not cleaned very often because there was little variation in the additives used.

Teta cites, as confirmatory evidence, four previous studies which she says have shown elevated risk of digestive cancer linked to PVC processing.

COMMENTS

The results of this new study bear careful consideration due to the strong excess cancer risk reported. However, its interpretation is complicated by the fact that, as with many other epidemiological studies, all the workers were exposed to a variety of different chemicals in the work place. This makes it impossible to prove that the excess cancer risk is associated with a specific chemical or combination of chemicals.

Dr. Teta stated that the observed excess in pancreatic cancer risk may have been due to practices early on in the industry which resulted in workers being exposed to high concentrations of a variety of chemicals associated with PVC manufacturing. Dr. Teta acknowledged that she was not very familiar with current PVC processing and formulating operations, such as the phasing out of lead and cadmium-based stabilizers. It would be helpful for the industry to document the changes in processes and work practice which have occurred over the years.

I am not aware to what degree Dr. Teta is aware of the toxicological controversy about the potential human carcinogenicity of diethylhexyl phthalate. Many reputable scientists question whether the results obtained in animal studies on this material are applicable to humans.

I think we should ask Dr. Teta to give a presentation on her study to the Vinyl Institute.

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A Division of The Society of The Plastics Industry, Inc.

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