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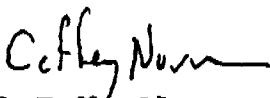
November 18, 1996

MEMORANDUM FOR THE HAP TASK FORCE

Re: 1,1,2-Trichloroethane Reproductive and Developmental Toxicity

Attached, as discussed at the meeting last week, is a proposed insert to the ECA proposal for 1,1,2-trichloroethane addressing the absence of need for reproductive or developmental toxicity testing. You will note a number of statements which need to be confirmed. Most of these relate to our assertion that 1,1,2-trichloroethane is linked to EDC production; the TRI data may indicate otherwise. I will look primarily to Bill Hayes for assistance on this issue, but would be pleased to hear from any of you if you have information.

Please let us have any comments by close of business Wednesday, November 20.


W. Caffey Norman, III

Attachment

cc: Michael L. Gargas, Ph.D.

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5.0 Developmental and Reproductive Toxicity Studies. With the exception of a postnatal mouse screening test, no study of the developmental or reproductive toxicity of 1,1,2-trichloroethane has been identified in the scientific literature. Accordingly, it is not possible to use route-to-route extrapolation to determine the developmental or reproductive effects of 1,1,2-trichloroethane following inhalation exposure. As discussed below, however, any concern as to developmental or reproductive risk posed by 1,1,2-trichloroethane is largely theoretical, based on the extremely low level of human exposure and EPA's position, accepted by the HAP Task Force, that 1,1,2-trichloroethane ^{can} should be regulated as a potential carcinogen. It should also be noted that structurally similar compounds, such as 1,1,1-trichloroethane and ethylene dichloride (EDC), have not shown significant developmental or reproductive toxicity when tested [Confirm].

Check for profiles 1,1,1 trichloroethane

The extremely low human exposure to 1,1,2-trichloroethane is due to the fact that virtually the entire U.S. production of 1,1,2-trichloroethane is as a captive or "site-limited" intermediate, ^{in the production of VDC or} generally as a byproduct of the production of EDC. ^{where in most many cases the 1,1,2- is not isolated. VDC or} Thus, 1,1,2-trichloroethane is found primarily in the vicinity of EDC production facilities [Confirm]. The one manufacturer that markets 1,1,2-trichloroethane sells less than ³ million pounds annually [Confirm].

Available data on the concentrations of 1,1,2-trichloroethane in the environment are consistent with the foregoing paragraph. The Agency for Toxic Substances and Disease Registry (ATSDR) has stated that "[w]here 1,1,2-trichloroethane is found, levels appear to be about 10-50 ppt [parts per trillion]."

Toxicological Profile for 1,1,2-Trichloroethane (1989), 63. These

These small groups (less than 10) of customers use 1,1,2 as a carrier solvent in the manufacture of other materials. Two of these customers have indicated that they will switch to alternate materials. These customers also recycle/recover the material as much as possible.

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concentrations would have been undetectable without advances in detection capability. The low environmental exposure is consistent with available information as to use. ATSDR found that "[n]o use with significant consumer and general population exposures has been identified." *Id.*, 61. Moreover, there is some doubt as to whether 1,1,2-trichloroethane meets the criteria articulated in EPA's so-called "B policy" for "substantial release" and "substantial human exposure," as will be addressed in greater detail in the comments of the HAP Task Force on the proposed test rule. For present purposes, it may be noted that the preamble to the proposed test rule does not identify any exposure as meeting the threshold for "substantial human exposure" except for 1,036 workers -- the threshold being 1,000 workers. The HAP Task Force will be providing a better estimate of the number of workers actually exposed to 1,1,2-trichloroethane as part of its comments. } not sure we can do this?

On top of the fact that human exposure to this site-limited intermediate is extremely low, EPA's regulatory structure would appear to make superfluous any determination as to the reproductive or developmental toxicity of 1,1,2-trichloroethane. As discussed above, the most significant potential exposure would appear to be from production facilities for ^{UDC or}EDC ^{UDC,} [Confirm]. Both EDC and 1,1,2-trichloroethane obviously are subject to regulation under the MACT standards for chemical production facilities, and any additional controls imposed as part of the residual risk determination for ^{UDC or}EDC will reduce exposure to 1,1,2-trichloroethane [Confirm]. The Agency's Integrated Risk Information System (IRIS) lists a unit risk estimate or cancer potency for 1,1,2-trichloroethane of 1.6×10^{-5} . The maximum 8-hour time-weighted-average (TWA) exposure allowed for

