VIDENCE REPORTEDLY GROWING ON VINYL CHLORIDE-BREAST CANCER LINK V c M

Vinyl chloride (VC) inhalation tests on rats conducted under contract for the National Institute for Environmental Health Sciences (NIEHS) reportedly have shown induction of malignant mammary tumors at levels below 50 parts per million. Significantly, none of the tumors appear in control groups which inhaled no VC.

The preliminary results, revealed to PESTICIDE & TOXIC CHEMICAL NEWS by one of nine Environmental Protection Agency officials who have been asked to comment on new VC data from Italian researcher Cesare Maltoni, lend credence, the source said, to allegations by the Environmental Defense Fund (EDF), that EPA's air emission standard for VC does not offer an adequate margin of safety to people living near plants which emit the chemical.

The Maltoni data, released in late September by the Society for the Plastics Industry (SPI), was cited by EDF in a recent petition asking the U. S. Court of Appeals in Washington, D.C., to review the EPA standard (See Dec. 15, Page 18). EDF cited the Maltoni data because it showed induction of malignant mammary tumors at levels as low as 1 p.p.m., far below the 50 p.p.m. level on which the EPA standard was based. However, because some malignant mammary tumors in the new Maltoni experiments also were found in rats which inhaled no VC, the sponsor of the Italian researcher, the Council of European Chemical Industry Federations, said "a quantitative evaluation" of Maltoni's results cannot be drawn at this time.

Maltoni himself, as well as critics of his work have raised the possibility that the tumors are not VC-related. The EPA official, however, who asked not to be identified, said that preliminary results from an NIEHS contract with Midwest Research Institute show no malignant mammary tumors in controls and replicate induction of these tumors at levels below 50 p.p.m. In addition, the source said, the NIEHS study shows more higher-dosed animals with the tumors than animals inhaling lower doses. This dose-response is not clear from the new Maltoni data circulated by SPI.

RECEIVED
RESEARCH & DEVELOPMENT
JAN 20 1977
W. M. SMITH

Finally, according to our EPA source, the NIEHS study shows that animals receiving the higher doses contract the tumors earlier than the lower-dosed animals. The SPI report on the Maltoni studies gives no details on when the first tumors were discovered in each dose group of test animals.

Maltoni, in a summary of his new data which was sent to EPA, the National Institutes of Health and the Food and Drug Administration, said he is currently reviewing all of his VC experiments to try to make some sense out of the varying rates of spontaneous onset of the mammary tumors even among controls.

> As outlined in the summary, Maltoni's new studies show that of 45, 51, 62 and 49 surviving Sprague-Dawley rats inhaling 25, 10, 5 and 1 p.p.m. VC respectively for 4 hours per day, 5 days per week for 52 weeks, 10, 12, 13 and 8 of the rats had malignant mammary tumors at 87 weeks. Of 49 surviving rats which had inhaled no VC, 4 had the tumors. In Maltoni's second recent experiment, where the dosage rate was 50 p.p.m. and all other factors were the same, malignant mammary tumors appeared at 100 weeks in 45 of 55 survivors and in 5 of 28 surviving controls.

EPA's air emission standard is based on documented worker cases of angiosarcoma, a rare liver disease, backed by previous Maltoni data showing angiosarcoma in Sprague-Dawley rats exposed to 50 p.p.m. VC. In those previous experiments, none of the controls had malignant mammary tumors, and since only 2 of 59 survivors in the treated group contracted the tumors, the EPA standard mentions the breast cancer risk only peripherally.

The EPA source said that EDF, which jumped on SPI's release of the new Maltoni data, is "kicking a dead horse" by asking court review of the EPA standard. Promulgation of the standard "took three years of hard negotiation with the industry," the source said. Still, he conceded that on the basis of the NIEHS and the new Maltoni data, environmentalists and public interest groups could claim that the high U.S. rate of breast cancer is attributable to VC exposure.

As scientists scurry for answers on the significance of the mammary tumors in control Goodyear Tire and Rubber Company and Air Products Chemicals, Inc. have filed motion to intervene in the EDF challenge to EPA's standard. There has been no ruling yet on these motions or the one filed earlier by SPI.

The nine EPA officials who have been asked by Jack Farmer, chief of the EPA standards development branch in Research Triangle Park, N.C., to comment on the new Maltoni data are John Knelson, Arnold Kuzmack, William Marcus, Robert McGaughy,* Ron Naveen, John O'Connor, Larry Plumlee, Jim Smith and Orin Stopinski.

* see R. E. Clark, V.P., Technical Director of MCA to McGaughy dated 1/14/77. (Distributed by hand 1/19/77).