

ECETOC Document

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ECETOC Statement on Formaldehyde

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ECETOC STATEMENT ON FORMALDEHYDE

A conference on formaldehyde toxicity took place in the U.S.A. in Nov. 1980. Provisional information after termination of the 24-month exposure period of rat and mouse formaldehyde inhalation studies, carried out by the Chemical Industry Institute of Toxicology (USA), was presented together with other findings.

The CIIT study involved the exposure of both rats and mice, in groups of 240 (120 per sex of each species) at each of three exposure levels (15, 6 and 2 ppm) for 6 hours per day, 5 days per week for two years. At the end of the 24-month exposure period, 95 of the rats exposed to 15 ppm of formaldehyde had developed cancers of the nasal passages, as had 3 of the rats exposed to 6 ppm formaldehyde. No such tumours were observed in rats exposed to 2 ppm nor in the controls. Two mice out of the 85 so far investigated, exposed at the highest level of 15 ppm, were found to have developed nasal cancer, but no such cancers were observed in the mice exposed to lower levels, nor in the control group.

Chronic tissue changes were observed in the nasal cavities of rats at all dose levels, and of mice exposed to 6 and 15 ppm formaldehyde vapour after 24 months. Animals maintained without exposure for 3 months after the 24-month exposure period showed some regression of these observed chronic tissue changes.

Completion and evaluation of the remaining experimental work is necessary before conclusions can be drawn from this study, particularly as formaldehyde is a normal metabolic product. The nasal cancers have occurred only at concentrations that produce chronic tissue irritation, and there is no indication that at non-irritant levels cancers would develop. The observed regression of these changes following cessation of formaldehyde exposure may also be important in the final evaluation.

The animal toxicological studies have been paralleled by a number of epidemiological studies to discover whether at levels of a few ppm there were any human health effects due to exposure to formaldehyde. Results of studies in the U.S.A., in the chemical industry and in some groups of embalmers who use formaldehyde (total 5.600 people) have shown neither nasal tumours nor any excess of respiratory cancer. The results of these studies have still to be fully reported. In addition, a group in the UK Chemical Industries Association has examined the medical records from a number of major producers and users of formaldehyde, and this has not revealed a single case of nasal cancer.

Further epidemiological studies in the U.S.A. and Europe are in progress or planned and should provide more valuable information to enable the relevance to humans of the results from the animal experiments to be assessed.

ECETOC emphasises the need for control of exposure to formaldehyde in compliance with nationally-recommended exposure limits.