

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

July 12, 1988

TO: AQD Permit Engineers
FROM: Catherine Simon
SUBJECT: Formaldehyde (CAS No. 50-00-0)

The cancer risk assessment for formaldehyde has changed slightly due to a recent review of the data for this compound. Based upon the current risk assessment, the estimated incremental unit risk value for formaldehyde is 1.3×10^{-5} , which is the value currently being used by the U.S. EPA. The incremental unit risk value is defined as the additional lifetime risk that would result in a population in which all individuals were exposed for a lifetime to 1 ug/m^3 of the chemical. Based upon this unit risk value, the concentration of formaldehyde in air resulting in an estimated increased risk of one in one million (1×10^{-6}) is 0.08 ug/m^3 . The U.S. EPA has classified formaldehyde as a "Probable Human Carcinogen" (Group B1). This classification is based upon the finding of sufficient evidence of carcinogenicity in animals and limited evidence in humans.

CAS:mh
cc: District Supervisors

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

July 5, 1988

TO: File

FROM: Catherine Simon

SUBJECT: Formaldehyde - CAS No. 50-00-0

Formaldehyde has been shown to be carcinogenic in laboratory animals in three different studies (Kerns et al, 1983; Albert et al, 1982; and Tobe et al, 1985). In all three studies a significantly increased incidence of squamous cell carcinoma of the nasal cavity was observed in rats exposed to formaldehyde by inhalation. Additionally, in the study sponsored by the Chemical Industry Institute of Toxicology (CIIT) (Kerns et al, 1983), although not statistically significant, a small number of similar tumors were observed in male mice exposed to formaldehyde. Because squamous cell carcinomas of the nasal cavity are rarely found in mice, these data are considered biologically significant. Based upon the above data there is sufficient evidence that formaldehyde is carcinogenic in laboratory animals.

The epidemiology studies conducted to date are inadequate to conclusively prove or disprove that formaldehyde is carcinogenic in humans. Many epidemiology studies have been conducted, however, most suffer from some type of limitation that potentially affects their conclusion and statistical power to detect increased cancer risks. While several negative epidemiology studies exist, several studies have also shown a statistically significant association between various types of cancer and exposure to formaldehyde containing products. Scientific consensus regarding the interpretation and significance of the epidemiology data does not exist.

The U.S. EPA (EPA, 1987) has recently reviewed the epidemiology data, including 28 studies, and concluded there is "limited" human evidence for the carcinogenicity of formaldehyde. This means that "a causal interpretation is credible, but that alternative explanations such as chance, bias, or confounding could not be adequately addressed." The classification of limited evidence is mainly due to possible exposure to other agents which may have confounded the findings of excess cancer.

Based upon all the available data, EPA has classified formaldehyde as a "Probable Human Carcinogen" (Group B1), under its Guidelines for Carcinogen Risk Assessment (51 FR 33992).

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A quantitative risk assessment was done by the U.S.EPA (EPA, 1987) to determine the incremental unit risk value for formaldehyde. The incremental unit risk value is defined as the additional lifetime cancer risk that would result in a population in which all individuals were exposed for a lifetime to 1 ug/m^3 of the chemical. The linearized multistage model was fit to the dose-response data from the CIIT study to determine the unit risk value. In this study, male and female Fischer 344 rats were exposed by inhalation to 0, 2.0, 5.6, and 14.3 ppm of formaldehyde for 6 hours per day, 5 days per week for up to a lifetime. A significantly increased incidence of squamous cell carcinoma of the nasal cavity was observed in both male and female rats. Because several animals were sacrificed or died early, an adjustment for the data input to the model had to be made. Therefore, rats that died prior to the appearance, at 11 months, of the first squamous cell carcinoma of the nasal cavity, were not considered at risk, and were excluded from the analysis. Rats sacrificed at 12 and 18 months were handled as if they would have responded in the same manner as those that remained alive after the respective sacrifice. The adjusted dose-response data used in the quantitative risk assessment is as follows.

<u>Dose (ppm)</u>	<u>Tumor Incidence</u>
0	0/156
2	0/159
5.6	2/153
14	94/150

Fitting the above data to the linearized multistage model resulted in a unit risk value of 1.3×10^{-5} . This value is recommended for use in estimating the increased cancer risk from exposure to low levels of formaldehyde. Using this unit risk value, the concentration of formaldehyde in air resulting in an increased risk of one in one million (1×10^{-6}) is 0.08 ug/m^3 .

CAS:mh
References

REFERENCES

- Albert, R.E. et al. 1982. Gaseous formaldehyde and hydrogen chloride induction of nasal cancer in the rat. J. Natl. Cancer Institute 68:597-603.
- Kerns, W.D. et al. 1983. Carcinogenicity of formaldehyde in rats and mice after long-term inhalation exposure. Cancer Research 43:4382-4392.
- Tobe M. et al. 1985. Studies of the inhalation toxicity of formaldehyde. National Sanitary and Medical Laboratory Service (Japan) pp. 1294. As cited in U.S. EPA (1987).
- U.S. Environmental Protection Agency (EPA). 1987. Assessment of Health Risks to Garment Workers and Certain Home Residents from Exposure to Formaldehyde. Final Draft. March 1987.