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TOXICOLOGICAL REVIEW OF FORMALDEHYDE - INHALATION ASSESSMENT

(CAS No. 50-00-0)

In Support of Summary Information on the Integrated Risk Information System (IRIS)

VOLUME I of IV

Introduction, Background, and Toxicokinetics

June 2, 2010

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U.S. Environmental Protection Agency
Washington, DC

4.5.3). [If

Table 5-26. Summary of inhalation unit risk estimates

Cancer type[a]	Dose metric	Unit risk estimate (ppm^{-1})
Based on epidemiologic data		
Nasopharyngeal	Cumulative exposure	0.011
Hodgkin lymphoma	Cumulative exposure	0.017
Leukemia	Cumulative exposure	0.057
Total cancer risk[b]	Cumulative exposure	0.081
Based on experimental animal data		
SCC of the respiratory tract	Local dose (flux) of formaldehyde in $pmol/mm^2$-hour	0.011–0.022

[a]The unit risk estimates are all for cancer incidence.
[b]The total cancer unit risk estimate is an estimate of the upper bound on the sum of risk estimates calculated for the 3 individual cancer types (nasopharyngeal cancer, Hodgkin lymphoma, and leukemia); it is not the sum of the individual (upper bound) unit risk estimates (see Section 5.2.4).

these estimates were to be used for benefit-cost analyses or some other purpose, ADAFs should be applied, as appropriate, in accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (U.S. EPA, 2005b), as discussed above and in Section 5.4.4.]

5.4.4. Application of Age-Dependent Adjustment Factors (ADAFs)

When there is sufficient weight of evidence to conclude that a mutagenic MOA is operative in a chemical's carcinogenicity and there are inadequate chemical-specific data to assess age-specific susceptibility, as is the case for formaldehyde (by inhalation exposure; see Section 5.4.3), EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (U.S. EPA, 2005b) recommends the application of default ADAFs to adjust for potential increased susceptibility from early-life exposure (see U.S. EPA [2005b] for detailed information on the general application of these adjustment factors). In brief, EPA (2005b) establishes ADAFs for three specific age groups: 10 (for <2 years), 3 (for 2 to <16 years), and 1 (for 16 years and above). For risk assessments based on specific exposure assessments, the 10-fold and threefold adjustments to the unit risk estimates are to be