

US EPA ARCHIVE DOCUMENT

TABLE C-2-1

INHALATION CANCER RISK FOR INDIVIDUAL CHEMICALS: CARCINOGENS

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Description

This equation calculates the excess lifetime individual cancer risk from the average daily intake via inhalation of a COPC carcinogen. Uncertainties associated with this equation include:

- (1) COPC-specific *Inhalation CSF* values are unlikely to underestimate, and may overestimate, the carcinogenic potential of COPCs because of the choice of mathematical models and the use of uncertainty factors on the estimation of these values.
- (2) COPC-specific *URF* values are unlikely to underestimate, and may overestimate, the carcinogenic potential of a COPC because of the choice of mathematical models and the use of uncertainty factors in the estimation of these values.
- (3) The uncertainty associated with the variable C_a are largely site-specific.
- (4) The uncertainties associated with the remaining variables in the equation in Table C-2-1, *IR*, *ET*, *EF*, *ED*, *BW*, and *AT* are not expected to be significant.

Equation

$$\text{Cancer Risk}_{inh(i)} = ADI \cdot CSF_{inh(i)}$$

$$ADI = \frac{C_a \cdot IR \cdot ET \cdot EF \cdot ED \cdot 0.001 \text{ mg}/\mu\text{g}}{BW \cdot AT \cdot 365 \text{ day/yr}}$$

$$CSF_{inh(i)} = \frac{URF \cdot 70 \text{ kg} \cdot 10^3 \mu\text{g}/\text{mg}}{20 \text{ m}^3/\text{day}}$$

Variable	Description	Units	Value
$\text{Cancer Risk}_{inh(i)}$	Individual lifetime cancer risk through direct inhalation of COPC carcinogen <i>i</i>	unitless	
<i>ADI</i>	Average daily COPC intake via inhalation	mg COPC/ kg-day	

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Variable	Description	Units	Value
<i>Inhalation CSF</i>	Inhalation Cancer Slope Factor	$(\text{mg/kg-day})^{-1}$	Varies This variable is COPC-specific, and should be determined from the COPC tables in Appendix A-3 . Uncertainty associated with this variable includes: Inhalation COPC-specific carcinogenic slope factors (<i>Inhalation CSF</i>) are generally estimated by fitting the results of studies conducted on laboratory animals with a mathematical model. The model generally recommended by U.S. EPA is the linearized multistage (LMS) model; U.S. EPA's position on assessing carcinogenic potential was recently updated (U.S. EPA 1996b). This model assumes that there is no "safe dose" or threshold below which a COPC causing cancer and higher doses will no longer cause cancer in exposed individuals. In other words, any exposure to a carcinogen may, through a series of stages, result in the formation of cancer in an exposed individual. Also, before fitting the results with the LMS model, the results are adjusted by the application of a series of uncertainty factors. The application of uncertainty factors follows the underlying assumption that humans are, or may be, as sensitive or more sensitive to the carcinogenic effects of COPCs than the laboratory COPCs that were tested. As a result, of both the choice of models and the use of uncertainty factors, COPC-specific <i>Inhalation CSF</i> are unlikely to underestimate a COPC's potential for causing cancer.
<i>URF</i>	Inhalation Unit Risk Factor	$(\mu\text{g/m}^3)^{-1}$	Varies This variable is COPC-specific, and should be determined from the COPC tables in Appendix A-3. The following general uncertainty is associated with this variable: COPC-specific inhalation unit risk factors (<i>URFs</i>) are generally estimated by fitting the results of studies conducted on laboratory animals with a mathematical model. The model generally recommended by U.S. EPA is the linearized multistage (LMS) model. U.S. EPA's position on assessing carcinogenic potential was recently updated (U.S. EPA 1996b). The LMS model assumes that there is no "safe dose" or threshold below which a COPC causing cancer at higher doses will no longer cause cancer in expected individuals. In other words, any exposure to a carcinogen may, through a series of stages, cause cancer in an exposed individual. Also, before the results are fitted with the LMS model, series of uncertainty factors are applied to the results. The application of uncertainty factors follows the underlying assumption that humans are, or may be, as sensitive or more sensitive to the carcinogenic effects of COPCs than the laboratory animals that were tested. As a result of the choice of models and the use of uncertainty factors, COPC-specific <i>URFs</i> are unlikely to underestimate a COPC's potential for causing cancer.

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Variable	Description	Units	Value
C_a	Total COPC air concentration	$\mu\text{g}/\text{m}^3$	Varies This variable is COPC- and site-specific, and is calculated using the equation in Table B-5-1. Uncertainty associated with this variable includes: Calculated assuming a default S_T value for background plus local sources, rather than a S_T value for urban sources. If a specific site is located in an urban area, the use of the letter S_T value may be more appropriate. Specifically, the S_T value for urban sources is about one order of magnitude greater than the S_T value for background plus local sources and would result in a lower calculated F_v value; however, the F_v value is likely to be only a few percent lower.
IR	Inhalation rate	m^3/hr	0.30 or 0.63 This variable is site-specific. U.S. EPA OSW recommends using default values of 0.63 (adults) and 0.30 (children) in the absence of site-specific information. The recommended adult value is consistent with U.S. EPA (1991) and U.S. EPA (1994a). The recommended child value is greater than the inhalation rate proposed on U.S. EPA (1994b)—0.18 m^3/hr based simply on the adult inhalation rate multiplied by the ratio of child to adult body weight (15 kg/70 kg)—but is consistent with U.S. EPA (1997) and U.S. EPA (1996c). Uncertainty associated with this variable includes: The recommended inhalation rates do not consider individual respiratory or activity differences. Therefore, based on the individual and the activities that individual is engaged in, the recommended inhalation rates may under-or overestimate the actual rates. However, the degree of under-or overestimation is not expected to be significant.
ET	Exposure time	hrs/day	24 This variable is site-specific. U.S. EPA OSW recommends the use of this default value in the absence of site-specific data. Uncertainty associated with this variable includes: The recommended ET value assumes that an individual remains at a specific location 24 hours per day. In reality this is likely to be true only for a minority of the population including young children, their caregivers, and elderly or other individual who are sick. Therefore, this recommended value contributes to a degree of overestimation for much of the population. However, it must be noted that though an individual may not always be at a single location, that individual may continue to be exposed to emissions at an alternate location.

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Variable	Description	Units	Value																					
EF	Exposure frequency	days/yr	350 This variable is site-specific. U.S. EPA OSW recommends the use of this default value in the absence of site-specific data. This value is based on U.S. EPA (1991) and is consistent with U.S. EPA (1994b). Uncertainties associated with this variable include: (1) This exposure frequency is a single value that represents the most frequent exposure that is reasonably expected to occur at a site with two weeks of vacation. This recommended value may overestimate <i>EF</i> for individuals who are away from their home for more than two weeks each year. On the other had, some individuals such as subsistence farmers, may remain at their home (or farm) for more than 350 days per year. In either case, the degree of over- or underestimation is not expected to be significant in most cases.																					
ED	Exposure duration	yr	6, 30, or 40 This variable is site-specific. Consistent with U.S. EPA (1994b), U.S. EPA OSW recommends the use of the following default values. <table><tr><td><u>Exposure Scenario</u></td><td><u>ED</u></td><td></td></tr><tr><td>Subsistence Farmer</td><td>40</td><td>(U.S. EPA 1994a)</td></tr><tr><td>Subsistence Farmer Child</td><td>6</td><td>(U.S. EPA 1989)</td></tr><tr><td>Subsistence Fisher</td><td>30</td><td>(U.S. EPA 1994a)</td></tr><tr><td>Subsistence Fisher Child</td><td>6</td><td>(U.S. EPA 1989)</td></tr><tr><td>Adult Resident</td><td>30</td><td>(U.S. EPA 1989)</td></tr><tr><td>Child Resident</td><td>6</td><td>(U.S. EPA 1989)</td></tr></table> Uncertainties associated with this variable include: (1) These exposure durations are single values that represent the highest exposure that is reasonably expected to occur at a site. These values may overestimate <i>ED</i> for some individuals.	<u>Exposure Scenario</u>	<u>ED</u>		Subsistence Farmer	40	(U.S. EPA 1994a)	Subsistence Farmer Child	6	(U.S. EPA 1989)	Subsistence Fisher	30	(U.S. EPA 1994a)	Subsistence Fisher Child	6	(U.S. EPA 1989)	Adult Resident	30	(U.S. EPA 1989)	Child Resident	6	(U.S. EPA 1989)
<u>Exposure Scenario</u>	<u>ED</u>																							
Subsistence Farmer	40	(U.S. EPA 1994a)																						
Subsistence Farmer Child	6	(U.S. EPA 1989)																						
Subsistence Fisher	30	(U.S. EPA 1994a)																						
Subsistence Fisher Child	6	(U.S. EPA 1989)																						
Adult Resident	30	(U.S. EPA 1989)																						
Child Resident	6	(U.S. EPA 1989)																						
BW	Body weight	kg	15 or 70 This variable is site-specific. U.S. EPA OSW recommends using default values of 70 (adults) and 15 (children) in the absence of site-specific information. These default values are consistent with U.S. EPA (1991; 1994b). Uncertainties associated with this variable include: (1) These body weights represent the average weight of an adult and child. However, depending on the site, the body weights may be higher or lower. These default values may overestimate or underestimate actual body weights. However, the degree of under- or overestimation is not expected to be significant.																					

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Variable	Description	Units	Value
AT	Averaging time	yr	70 This variable is site-specific. U.S. EPA OSW recommends the use of this default value in the absence of site-specific data. This default value is consistent with U.S. EPA (1989), U.S. EPA (1991), and U.S. EPA (1994b). Uncertainties associated with this variable include: (1) The recommendation for averaging time may not accurately represent site-specific time; specifically this single value may under- or overestimate the length of an average adult lifetime.

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REFERENCES AND DISCUSSION

U.S. EPA. 1989. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)*. Interim Final. Office of Emergency and Remedial Response. EPA/540/1-89/002. December.

This document is cited as the reference source document of the exposure duration for adult and child residents. U.S. EPA assumes that the recommended exposure duration for the child resident may also reasonably be applied to the subsistence farmer child and to the subsistence fisher child. This document is also cited as reference source document for the averaging time for carcinogens.

U.S. EPA. 1991. *Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors*. Office of Solid Waste and Emergency Response. OSWER Directive 9285.6-03. Washington, D.C. March 21.

This document is cited as the reference source document of the exposure frequency and body weight variables.

U.S. EPA. 1994a. *Estimating Exposure to Dioxin-like Components - Volume III: Site-Specific Assessment Procedure*. Review Draft. Office of Research and Development. Washington D.C. EPA/600/6-88/005Cc. June.

This document is cited by U.S. EPA (1994b) as the same document for the recommended default exposure duration (ED) values for the subsistence farmer and subsistence fisher. The ED value of 40 years recommended for both the subsistence farmer and the subsistence fisher is based on the assumption that “farmers live in one location longer than the general population”.

U.S. EPA. 1994b. *Revised Draft Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes. Attachment C, Draft Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities*. Office of Emergency and Remedial Response. Office of Solid Waste. December 14.

This document recommends the following:

- An adult inhalation rate of 20 m³/day (0.83 m³/hr) and a child inhalation rate of 7.2 m³/day (0.3 m³/hr)—based on multiplying the adult rate by the ratio of child to adult body weight (15 kg/70 kg).
- An exposure frequency of 350 days per year
- Receptor-specific exposure duration values as presented in U.S. EPA (1994a)—subsistence fisher (40 years) and subsistence farmer (40 years) and U.S. EPA (1989)—adult resident (30 years) and child resident (6 years)
- Adult and child body weights of 70 kg and 15 kg, respectively
- An averaging time, AT, of 70 years

U.S. EPA. 1994c. *Health Effects Assessment Summary Tables. Annual Update*. OHEA-ECAO-CIN-909. Environmental Criteria and Assessment Office, Office of Research and Development Cincinnati, Ohio.

This document represents U.S. EPA's secondary source of *Inhalation CSF* values.

U.S. EPA. 1996a. “Integrated Risk Information System (IRIS)”. *Database on Toxicity Information Network (TOXNET)*.

This reference represents U.S. EPA's primary source of *Inhalation CSF* values and other toxicity factors. This reference is updated periodically and should be reviewed prior to preparing a risk assessment.

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U.S. EPA. 1996b. "Proposed Guidelines for Carcinogenic Risk Assessment." *Federal Register*. 61 FR 31667. Volume 61. Number 120. June 20.

This document proposes new guidelines for assessing the carcinogenicity of COPCs.

U.S. EPA. 1996c. "EPA Region IX Preliminary Remediation Goals (PRGs) -- 1996." August 1.

This document recommends a reasonable maximum exposure (RME) inhalation rate for children of 10 m³/day, citing U.S. EPA (1989) as its source of information.

U.S. EPA. 1997. *Exposure Factors Handbook*. Office of Research and Development. EPA/600/P-95/002F. August.

This document recommends an "average" child inhalation of 7.17 m³/day (0.30 m³/hr), and an "average" adult inhalation rate of 15.2 m³/day (0.63 m³/hr).