

PRE-REGULATORY DRAFT-FOR DISCUSSION PURPOSES ONLY

Title 27, California Code of Regulations
ARTICLE 8. No Observable Effect Levels

§ 25821. Level of Exposure to Chemicals Causing Reproductive Toxicity

(a) For purposes of the Act, “level in question” means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing reproductive toxicity shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

(c) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available:

(1) The assumptions set forth in subsection (d) of Section 25721 shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available.

(2) For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. This rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

(3) Where a maternal exposure to a chemical listed as causing reproductive toxicity has an effect on the conceptus (embryo or fetus), the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.