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## 40 C.F.R. § 798.4350

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### Inhalation developmental toxicity study.

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- (a) *Purpose.* In the assessment and evaluation of the toxic characteristics of an inhalable material such as a gas, volatile substance, or aerosol/particulate, determination of the potential developmental toxicity is important. The inhalation developmental toxicity study is designed to provide information on the potential hazard to the unborn which may arise from exposure of the mother during pregnancy.
- (b) *Definitions.* (1) Developmental toxicity is the property of a chemical that causes in utero death, structural or functional abnormalities or growth retardation during the period of development.
- (2) “Aerodynamic diameter” applies to the behavioral size of particles of aerosols. It is the diameter of a sphere of unit density which behaves aerodynamically like the particles of the test substance. It is used to compare particles of different sizes, shapes, and densities and to predict where in the respiratory tract such particles may be deposited. This term is used in contrast to “optical,” “measured” or “geometric” diameters which are representation of actual diameters which in themselves cannot be related to deposition within the respiratory tract.
- (3) “Geometric mean diameter” or “median diameter” is the calculated aerodynamic diameter which divides the particles of an aerosol in half based on the weight of the particles. Fifty percent of the particles by weight will be larger than the median diameter and 50 percent of the particles will be smaller than the median diameter. The median diameter and its geometric standard deviation are used to statistically describe the particle size distribution of any aerosol based on the weight and size of the particles.
- (4) “Inhalable diameter” refers to that aerodynamic diameter of a particle which is considered to be inhalable for the organism. It is used to refer to particles which are capable of being inhaled and may be deposited anywhere within the respiratory tract from the trachea to the deep lung (the alveoli). For man, the inhalable diameter is considered here as 15 micrometers or less.
- (5) “Concentration” refers to an exposure level. Exposure is expressed as weight or volume of test substance per volume of air (mg/1), or as parts per million (ppm).
- (6) “No-observed-effect level” is the maximum concentration in a test which produces no observed adverse effects. A no-observed-effect level is expressed in terms of weight or volume of test substance given daily per unit volume of air.
- (c) *Principle of the test method.* The test substance is administered in graduated concentrations, for at least that part of the pregnancy covering the major period of organogenesis, to several groups of pregnant experimental animals, one exposure level being used per group. Shortly before the expected date of delivery, the pregnant females are sacrificed, the uteri removed, and the contents examined for embryonic or fetal deaths, and live fetuses.
- (d) *Limit test.* If a test at an exposure of 5 mg/1 (actual concentration of respirable substances) or, where this is
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not possible due to physical or chemical properties of the test substance, the maximum attainable concentration, produces no observable developmental toxicity, then a full study using three exposure levels might not be necessary.

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