

40 C.F.R. § 798.4900

Developmental toxicity study.

- (a) *Purpose.* In the assessment and evaluation of the toxic characteristics of a chemical, determination of the potential developmental toxicity is important. The 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) Dose is the amount of test substance administered. Dose is expressed as weight of test substance (g, mg) per unit weight of a test animal (e.g., mg/kg).
- (3) 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 of test substance given daily per unit weight of test animal (mg/kg)
- (c) *Principle of the test method.* The test substance is administered in graduated doses for at least part of the pregnancy covering the major period of organogenesis, to several groups of pregnant experimental animals, one dose 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 at least 1000 mg/kg body weight, using the procedures described for this study, produces no observable developmental toxicity, then a full study using three dose levels might not be necessary.
- (e) *Test procedures—(1) Animal selection—(i) Species and strain.* Testing shall be performed in at least 2 mammalian species. Commonly used species include the rat, mouse, rabbit, and hamster. If other mammalian species are used, the tester shall provide justification/reasoning for their selection. Commonly used laboratory strains shall be employed. The strain shall not have low fecundity and shall preferably be characterized for its sensitivity to developmental toxins.

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