Environmental Protection Agency § 792.135

(4) The proposed experimental start and termination dates.
(5) Justification for selection of the test system.
(6) Where applicable, the number, body weight, sex, source of supply, species, strain, substrain, and age of the test system.
(7) The procedure for identification of the test system.
(8) A description of the experimental design, including methods for the control of bias.
(9) Where applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or reference substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.
(10) The route of administration and the reason for its choice.
(11) Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or reference substance to be administered and the method and frequency of administration.
(12) The type and frequency of tests, analyses, and measurements to be made.
(13) The records to be maintained.
(14) The date of approval of the protocol by the sponsor and the dated signature of the study director.
(15) A statement of the proposed statistical method.
(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

§ 792.135 Physical and chemical characterization studies.

(a) All provisions of the GLPs shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies).
(b) The following GLP standards shall not apply to studies designed to determine physical and chemical characteristics of a test, control, or reference substance:

Section 792.31 (c), (d), and (g)
Section 792.33 (b) and (c)
Section 792.43
Section 792.45
Section 792.47
Section 792.49
Section 792.81(b) (1), (2), (6) through (9), and (12)
Section 792.90
Section 792.105 (a) through (d)