

40 C.F.R. § 798.4100

Dermal sensitization.

- (a) *Purpose.* In the assessment and evaluation of the toxic characteristics of a substance, determination of its potential to provoke skin sensitization reactions is important. Information derived from tests for skin sensitization serves to identify the possible hazard to a population repeatedly exposed to a test substance. While the desirability of skin sensitization testing is recognized, there are some real differences of opinion about the best method to use. The test selected should be a reliable screening procedure which should not fail to identify substances with significant allergenic potential, while at the same time avoiding false negative results.
- (b) *Definitions.* (1) Skin sensitization (allergic contact dermatitis) is an immunologically mediated cutaneous reaction to a substance. In the human, the responses may be characterized by pruritis, erythema, edema, papules, vesicles, bullae, or a combination of these. In other species the reactions may differ and only erythema and edema may be seen.
- (2) Induction period is a period of at least 1 week following a sensitization exposure during which a hypersensitive state is developed.
- (3) Induction exposure is an experimental exposure of a subject to a test substance with the intention of inducing a hypersensitive state.
- (4) Challenge exposure is an experimental exposure of a previously treated subject to a test substance following an induction period, to determine whether the subject will react in a hypersensitive manner.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)