
40 C.F.R. § 82.178

Information required to be submitted.

(a) Persons whose substitutes are subject to reporting requirements pursuant to § 82.176 must provide the following information:

(1) *Name and description of the substitute.* The substitute should be identified by its: Chemical name; trade name(s); identification numbers; chemical formula; and chemical structure.

(2) *Physical and chemical information.* The substitute should be characterized by its key properties including but not limited to: Molecular weight; physical state; melting point; boiling point; density; taste and/or odor threshold; solubility; partition coefficients (Log K_{ow} , Log K_{oc}); atmospheric lifetime and vapor pressure.

(3) *Substitute applications.* Identification of the applications within each sector end-use in which the substitutes are likely to be used.

(4) *Process description.* For each application identified, descriptive data on processing, including in-place pollution controls.

(5) *Ozone depletion potential.* The predicted 100-year ozone depletion potential (ODP) of substitute chemicals. The submitter must also provide supporting documentation or references.

(6) *Global warming impacts.* Data on the total global warming potential of the substitute, including information on the GWP index and the indirect contributions to global warming caused by the production or use of the substitute (e.g., changes in energy efficiency). GWP must be calculated over a 100, 500 and 1000-year integrated time horizon.

(7) *Toxicity data.* Health and safety studies on the effects of a substitute, its components, its impurities, and its degradation products on any organism (e.g., humans, mammals, fish, wildlife, and plants). For tests on mammals, the Agency requires a minimum submission of the following tests to characterize substitute risks: A range-finding study that considers the appropriate exposure pathway for the specific use (e.g., oral ingestion, inhalation, etc.), and a 90-day subchronic repeated dose study in an appropriate rodent species. For certain substitutes, a cardiotoxicity study is also required. Additional mammalian toxicity tests may be identified based on the substitute and application in question. To sufficiently characterize aquatic toxicity concerns, both acute and chronic toxicity data for a variety of species are required. For this purpose, the Agency requires a minimum data set as described in “Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses,” which is available through the National Technical Information Service (#PB 85-227049). Other relevant information and data summaries, such as the Material Safety Data Sheets (MSDS), should also be submitted. To assist in locating any studies previously submitted to EPA and referred to, but not included in a SNAP submission, the submitter must provide citations for the date, type of submission, and EPA Office to which they were submitted, to help EPA locate these quickly.

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