

## Environmental Protection Agency

## § 716.60

(j) Degradation by biological mechanisms—aerobic and anaerobic.

### § 716.55 Confidentiality claims.

(a)(1) Section 14(b) of TSCA provides that EPA may not withhold from disclosure, on the grounds that they are confidential business information, health and safety studies of any substance or mixture that has been offered for commercial distribution (including for test marketing purposes and for use in research and development), any substance or mixture for which testing is required under TSCA section 4, or any substance for which notice is required under TSCA section 5, except to the extent that disclosure of data from such studies would reveal—

(i) Processes used in the manufacturing, importing, or processing of the substance or mixture, or

(ii) The portion of a mixture comprised by any of the substances in the mixture.

(2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because disclosure would reveal a confidential process or quantitative mixture composition should briefly state the basis of the claim, e.g., by saying “reveals confidential mixture proportion data,” and clearly identify the material subject to the claim.

(3) Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company. This information will not be subject to the disclosure requirements of section 14(b) of TSCA.

(4) Information other than company name or address, financial statistics, and product codes used by a company, which is contained in a study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), will be considered confidential by EPA as provided in Title 5, United States Code, section 552(b)(6).

(b) To assert a claim of confidentiality for data contained in a submitted document, the respondent must submit two copies of the document:

(1) One copy must be complete. In that copy, the respondent must indicate what data, if any, are claimed as

confidential by bracketing or underlining the specific information. Each page containing data claimed as confidential must also contain a brief statement for the basis of the claim as well as a label such as “confidential,” “proprietary,” or “trade secret.”

(2) The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted. The second copy will be immediately subject to public disclosure.

(3) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of his or her receipt of this notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

(c) If no claim of confidentiality accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

### § 716.60 Reporting schedule.

(a) *General requirements.* Except as provided in § 716.5 and paragraphs (b) and (c) of this section, submissions under §§ 716.30 and 716.35 must be post-marked on or before 60 days after the effective date of the listing of a substance or mixture in § 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in § 716.120.

(b)(1) *Submission of lists of initiated studies.* Persons subject to the listing requirements of § 716.35(a)(2) must inform EPA of the initiated study within 30 days of its initiation.

(2) *Submission of copies of completed studies.* Persons must submit copies of studies listed as ongoing or initiated