(v) Chemical substances that result from chemical reactions that occur when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation-inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH adjuster, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(b) [Reserved]

(c) *Sole distributors.* A person solely engaged in the distribution of chemical substances is exempt from this part, unless such person is also a manufacturer or processor subject to this part. For example, a "distributor" who repackages chemical substances or mixtures is considered to be a processor and, thus, is not a sole distributor. Sole distributors may include, but are not limited to, those firms that distribute chemical substances as described in the wholesale trade SIC codes 5161—Chemicals and Allied Products, 5171—Petroleum Bulk Stations and Terminals, and 5172—Petroleum and Petroleum Products Wholesalers, Except Bulk Stations and Terminals.

(d) *Retailers.* A person who is a retailer is exempt from this part unless such person is also a manufacturer or a processor subject to this part.

[48 FR 38187, Aug 22, 1983, as amended at 50 FR 46770, Nov. 13, 1985]

§ 717.10 Allegations subject to this part.

(a) Allegations subject to this part are those allegations received on or after November 21, 1983 by persons subject to this part.

(b) Allegations subject to this part are those that:

(1) Are submitted either in writing and are signed by the alleger, or are submitted orally. In the case of an oral allegation, the firm must transcribe the allegation into written form, or it must inform the alleger that such allegation may be subject to this part and request that the alleger submit such allegation to the firm in writing and signed.

(2) Implicate a substance that caused the stated significant adverse reaction by one of the following:

(i) Naming the specific substance.

(ii) Naming a mixture that contains a specific substance.

(iii) Naming an article that contains a specific substance.

(iv) Naming a company process or operation in which substances are involved.

(v) Identifying an effluent, emission, or other discharge from a site of manufacturing, processing or distribution of a substance.

(c) Allegations subject to this part may be made to a firm by any person, such as an employee of the firm, individual consumer, a neighbor of the firm's plant, another firm on behalf of its employees or an organization on behalf of its members.

(d) EPA intends that firms should, to the maximum practical extent, provide allegers with information regarding the ultimate disposition of their allegations. For example, firms could provide a brief notice to the alleger stating that a record was created under this part based upon their allegation, or that a record was not created and briefly explain the reasons why not.

§ 717.12 Significant adverse reactions that must be recorded.

(a) Except as provided in paragraph (b) of this section, significant adverse reactions to human health that must be recorded include but are not limited to:

(1) Long-lasting or irreversible damage, such as cancer or birth defects.

(2) Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders or blood disorders.

(3) An impairment of normal activities experienced by all or most of the persons exposed at one time.

(4) An impairment of normal activities which is experienced each time an individual is exposed.

(b) Firms are not required to record significant adverse reactions that are known human effects as defined in § 717.3(c).

(c) Except as provided in paragraph (d) of this section, significant adverse reactions to the environment that must be recorded, even if restricted to the environs of a plant or disposal site, include but are not limited to:

(1) Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area.

(2) Abnormal number of deaths of organisms (e.g., fish kills).

(3) Reduction of the reproductive success or the vigor of a species.

(4) Reduction in agricultural productivity, whether crops or livestock.

(5) Alterations in the behavior or distribution of a species.

(6) Long lasting or irreversible contamination of components of the physical environment, especially in the case of ground water, and surface water and soil resources that have limited self-cleansing capability.

(d) Firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the Federal Government under any applicable authority.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 58 FR 34204, June 23, 1993]

§ 717.15 Recordkeeping requirements.

(a) *Establishment and location of records.* A firm subject to this part shall establish and maintain records of significant adverse reactions alleged to have been caused by chemical substances or mixtures manufactured or processed by the firm. Such records shall be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations.

(b) *Content of records.* The record shall consist of the following:

(1) The original allegation as received.

(2) An abstract of the allegation and other pertinent information as follows:

(i) The name and address of the plant site which received the allegation.

(ii) The date the allegation was received at that site.

(iii) The implicated substance, mixture, article, company process or operation, or site discharge.

(iv) A description of the alleger (e.g., "company employee," "individual consumer," "plant neighbor"). If the allegation involves a health effect, the sex and year of birth of the individual should be recorded, if ascertainable.

(v) A description of the alleged health effect(s). The description must relate how the effect(s) became known and the route of exposure, if explained in the allegation.

(vi) A description of the nature of the alleged environmental effect(s), identifying the affected plant and/or animal species, or contaminated portion of the physical environment.

(3) The results of any self-initiated investigation with respect to an allegation. (EPA does not require persons subject to this part to investigate allegations received, and no provision of this part shall be construed to imply that EPA recommends, encourages or requires such investigation.)

(4) Copies of any further required records or reports relating to the allegation. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Form 101 or appropriate substitute (see 29 CFR part 1904 for requirements under the Occupational Safety and Health Act of 1970), a copy of that OSHA record must be included in the allegation record.

(c) *File structure.* Records must be retrievable by the alleged cause of the significant adverse reaction, which cause may be one of the following:

(1) A specific chemical identity.

(2) A mixture.

(3) An article.

(4) A company process or operation.

(5) A site emission, effluent or other discharge.

(d) *Retention period.* Records of significant adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. This provision requires persons subject to this part to retain for 30