

Environmental Protection Agency

§ 717.3

Category	CAS No.	Special Exemptions	Effective Date	Sunset Date
Thiazole, 4-methyl-	693-95-8	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
Thiourea	62-56-6	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
1,3,5-Triazine, hexahydro-1,3,5-trinitro-	121-82-4	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(6-isocyanatohexyl)-	3779-63-3	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
1,3,5-Triazine-2,4-diamine, dimethylethyl-N'-ethyl-, 6-chloro-N-(1,1-methylethyl)-	5915-41-3	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
1,3,5-Triazine-2,4-diamine, methylethyl-, 6-chloro-N,N'-bis(1-methylethyl)-	139-40-2	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
1,3,5-Triazine-2,4-diamine, 6-chloro-N-ethyl-N'-(1-methylethyl)-	1912-24-9	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
Urea, (hydroxymethyl)-	1000-82-4	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
Urea, N'-(3,4-dichlorophenyl)-N,N-dimethyl-	330-54-1	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
Urea, sulfate (1:1)	21351-39-3	§ 716.21(a)(7)	September 29, 2006	November 28, 2006
Urea, sulfate (2:1)	17103-31-0	§ 716.21(a)(7)	September 29, 2006	November 28, 2006

[53 FR 38645, Sept. 30, 1988]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 716.120, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 59 FR 14115, Mar. 25, 1994, in § 716.120 paragraph (d), the chemical substances under the category "propylene glycol ethers and esters" and all related dates, was stayed effective March 25, 1994.

PART 717—RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT

Subpart A—General Provisions

Subpart A—General Provisions

- Sec.
- 717.1 Scope and compliance.
- 717.3 Definitions.
- 717.5 Persons subject to this part.
- 717.7 Persons not subject to this part.
- 717.10 Allegations subject to this part.
- 717.12 Significant adverse reactions that must be recorded.
- 717.15 Recordkeeping requirements.
- 717.17 Inspection and reporting requirements.
- 717.19 Confidentiality.

AUTHORITY: 15 U.S.C. 2607(c).

SOURCE: 48 FR 38187, Aug. 22, 1983, unless otherwise noted.

§ 717.1 Scope and compliance.

Section 8 (c) of the Toxic Substances Control Act (TSCA) requires manufacturers, processors, and distributors of chemical substances and mixtures:

(a) To keep "records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture."

(b) To "permit inspection and submit copies of such records", upon request of any designated representative of the Administrator. This rule implements section 8(c) of TSCA. It describes the records to be kept and prescribes the conditions under which certain firms must submit or make the records available to a duly designated representative of the Administrator.

§ 717.3 Definitions.

The definitions set forth in section 3 of TSCA and the following definitions apply to this part:

(a) *Allegation* means a statement, made without formal proof or regard

§717.5

40 CFR Ch. I (7-1-07 Edition)

for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

(b) *Firm* or *company* means any person, that is subject to this part, as defined in §717.5.

(c)(1) *Known human effects* means a commonly recognized human health effect of a particular substance or mixture as described either in:

(i) Scientific articles or publications abstracted in standard reference sources.

(ii) The firm's product labeling or material safety data sheets (MSDS).

(2) However, an effect is not a "known human effect" if it:

(i) Was a significantly more severe toxic effect than previously described.

(ii) Was a manifestation of a toxic effect after a significantly shorter exposure period or lower exposure level than described.

(iii) Was a manifestation of a toxic effect by an exposure route different from that described.

(d) *Manufacture* or *process* means to manufacture or process for commercial purposes.

(e)(1) *Manufacture for commercial purposes* means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For distribution in commerce, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) *Manufacture for commercial purposes* also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substances or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of

the manufacture of a chemical product for a commercial purpose.

(f) *Person* includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, and any department, agency, or instrumentally of the Federal Government.

(g) *Process for commercial purposes* means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(h) *Retailer* means a person who distributes in commerce a chemical substance, mixture, or article to ultimate purchasers who are not commercial entities.

(i) *Significant adverse reactions* are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

(j) *Site* means a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be multiple manufacturing, processing, or distribution activities occurring within a single site.

(k) *Substance* means a chemical substance or mixture unless otherwise indicated.

§717.5 Persons subject to this part.

(a) *Manufacturers.* (1) All manufacturers of chemical substances are subject to this part except as provided in §717.7(a). If manufacture of a chemical substance occurs at any site owned or controlled by a firm then that firm is subject to this part.

(2) A manufacturer must collect:

(i) Any allegation identifying a chemical substance it manufactures and any allegation identifying the operations in the manufacture of any chemical substance it manufactures.

(ii) Any allegation identifying any of its own processing or distribution in