

rehabilitative efforts following the action. The registrant shall assess the risks involved in employing such persons, including the potential for action against the registrant pursuant to §1309.43. If such person is found to have diverted listed chemicals, and, in the event of employment, shall institute procedures to limit the potential for diversion of List I chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

**§ 1309.73 Employee responsibility to report diversion.**

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

**PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES**

Sec.  
1310.01 Definitions.

- 1310.02 Substances covered.
- 1310.03 Persons required to keep records and file reports.
- 1310.04 Maintenance of records.
- 1310.05 Reports.
- 1310.06 Content of records and reports.
- 1310.07 Proof of identity.
- 1310.08 Excluded transactions.
- 1310.09 Temporary exemption from registration.
- 1310.10 Removal of the exemption of drugs distributed under the Federal Food, Drug and Cosmetic Act.
- 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.
- 1310.12 Exempt chemical mixtures.
- 1310.13 Exemption of chemical mixtures; application.
- 1310.14 Removal of exemption from definition of regulated transaction.
- 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.
- 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

AUTHORITY: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

**§ 1310.01 Definitions.**

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

**§ 1310.02 Substances covered.**

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

- (a) List I chemicals
  - (1) Anthranilic acid, its esters, and its salts.....8530
  - (2) Benzyl cyanide.....8735
  - (3) Ephedrine, its salts, optical isomers, and salts of optical isomers .....8113
  - (4) Ergonovine and its salts .....8675
  - (5) Ergotamine and its salts.....8676
  - (6) N-Acetylanthranilic acid, its esters, and its salts.....8522

§ 1310.02

21 CFR Ch. II (4-1-12 Edition)

(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers .....8317

(8) Phenylacetic acid, its esters, and its salts.....8791

(9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers .....1225

(10) Piperidine and its salts .....2704

(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.....8112

(12) 3,4-Methylenedioxyphenyl-2-propanone .....8502

(13) Methylamine and its salts.....8520

(14) Ethylamine and its salts .....8678

(15) Propionic anhydride.....8328

(16) Isosafrole.....8704

(17) Safrole.....8323

(18) Piperonal.....8750

(19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine) .....8115

(20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers .....8119

(21) Hydriodic Acid .....6695

(22) Benzaldehyde.....8256

(23) Nitroethane.....6724

(24) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone) .....2011

(25) Red phosphorus .....6795

(26) White phosphorus (Other names: Yellow Phosphorus) .....6796

(27) Hypophosphorous acid and its salts (Including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite and sodium hypophosphite) .....6797

(28) N-phenethyl-4-piperidone (NPP).....8332

(29) Iodine .....6699

(30) Ergocristine and its salts 8612

(b) List II chemicals:

(1) Acetic anhydride.....8519

(2) Acetone .....6532

(3) Benzyl chloride .....8570

(4) Ethyl ether .....6584

(5) Potassium permanganate .....6579

(6) 2-Butanone (or Methyl Ethyl Ketone or MEK) .....6714

(7) Toluene .....6594

(8) Hydrochloric acid (including anhydrous hydrogen chloride) .....6545

(9) Sulfuric acid .....6552

(10) Methyl Isobutyl Ketone (MIBK) .....6715

(11) Sodium Permanganate .....6588

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

- (1) The name and address of the petitioner;
- (2) The name of the chemical to which the petition pertains;
- (3) The name and address of the manufacturer(s) of the chemical (if known);
- (4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;
- (5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested

persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 71 FR 60826, Oct. 17, 2006; 72 FR 20046, Apr. 23, 2007; 72 FR 35391, July 2, 2007; 72 FR 40238, July 24, 2007; 76 FR 17781, Mar. 31, 2011]

**§ 1310.03 Persons required to keep records and file reports.**

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or “end use” and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996; 67 FR 14861, Mar. 28, 2002; 68 FR 57804, Oct. 7, 2003; 70 FR 294, Jan. 4, 2005]

**§ 1310.04 Maintenance of records.**

(a) Every record required to be kept subject to § 1310.03 for a List I chem-

ical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person’s place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) For those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

(1) List I chemicals:

(i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals.

Code	Chemical	Threshold by base weight
8522 .....	N-Acetylanthranilic acid, its esters, and its salts .....	40 kilograms.
8530 .....	Anthranilic acid, its esters, and its salts .....	30 kilograms.
8256 .....	Benzaldehyde .....	4 kilograms.