

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to §1310.03 for a List I chemical, 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.

Chemical	Threshold by base weight
(A) Anthranilic acid, its esters, and its salts	30 kilograms.

Chemical	Threshold by base weight
(B) Benzyl cyanide .....	1 kilogram.
(C) Ergonovine and its salts .....	10 grams.
(D) Ergotamine and its salts .....	20 grams.
(E) N-Acetylanthranilic acid, its esters, and its salts.	40 kilograms.
(F) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(G) Phenylacetic acid, its esters, and its salts.	1 kilogram.
(H) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(I) Piperidine and its salts .....	500 grams.
(J) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
(K) 3,4-Methylenedioxyphenyl-2-propanone	4 kilograms.
(L) Methylamine and its salts .....	1 kilogram.
(M) Ethylamine and its salts .....	1 kilogram.
(N) Propionic anhydride .....	1 gram.
(O) Isosafrole .....	4 kilograms.
(P) Safrole .....	4 kilograms.
(Q) Piperonal .....	4 kilograms.
(R) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine).	1 kilogram.
(S) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
(T) Hydriodic Acid .....	1.7 kilograms (or 1 liter by volume).
(U) Benzaldehyde .....	4 kilograms.
(V) Nitroethane .....	2.5 kilograms.

(ii) Notwithstanding the thresholds established in paragraphs (f)(1)(i) and (g) of this section, the following thresholds will apply for the following List I chemicals that are contained in drug products that are regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter (thresholds for retail distributors and distributors required to report under §1310.03(c) of this part are for a single transaction; the cumulative threshold provision does not apply. All other distributions are subject to the cumulative threshold provision.):

Chemical	Threshold by weight
(A) Ephedrine, its salts, optical isomers, and salts of optical isomers as the sole therapeutically significant medicinal ingredient.	No threshold. All transactions regulated.
(B) Ephedrine, its salts, optical isomers, and salts of optical isomers in combination with therapeutically significant amounts of another medicinal ingredient:	
(1) Distributions by retail distributors ....	24 grams.
(2) Distributions by persons required to report under § 1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports .....	1 kilogram
(C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors ....	24 grams.

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Chemical	Threshold by weight
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions, (other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports .....	1 kilogram.
(D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors ....	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports .....	1 kilogram.
(E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors ....	24 grams.

Chemical	Threshold by weight
(2) Distributions by persons required to report under § 1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section).	2.5 kilograms.
(4) Imports and Exports .....	2.5 kilograms.
(F) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors ....	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(F) (1) and (2) of this section).	2.5 kilograms.
(4) Imports and Exports .....	2.5 kilograms.

(2) List II Chemicals:  
(i) Imports and Exports

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride .....	250 gallons .....	1,023 kilograms.
(B) Acetone .....	500 gallons .....	1,500 kilograms.
(C) Benzyl chloride .....	N/A .....	4 kilograms.
(D) Ethyl ether .....	500 gallons .....	1,364 kilograms.
(E) Potassium permanganate .....	N/A .....	500 kilograms.
(F) 2-Butanone (MEK) .....	500 gallons .....	1,455 kilograms.
(G) Toluene .....	500 gallons .....	1,591 kilograms.

(ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride .....	250 gallons .....	1,023 kilograms.
(B) Acetone .....	50 gallons .....	150 kilograms.
(C) Benzyl chloride .....	N/A .....	1 kilogram.
(D) Ethyl ether .....	50 gallons .....	135.8 kilograms.
(E) Potassium permanganate .....	N/A .....	55 kilograms.
(F) 2-Butanone (MEK) .....	50 gallons .....	145 kilograms.
(G) Toluene .....	50 gallons .....	159 kilograms.
(H) Iodine .....	N/A .....	0.4 kilograms.
(I) Anhydrous Hydrogen chloride .....	N/A .....	0.0 kilograms.

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

(iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in §1310.08(b).

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid (1) Anhydrous Hydrogen chloride.	50 gallons .....	27 kilograms.
(B) Sulfuric acid .....	50 gallons	

(v) Export and International Transactions to Designated Countries, and

Importations for Transshipment or Transfer to Designated Countries

Chemical	Threshold by volume	Threshold by weight
(A) Methyl Isobutyl Ketone (MIBK).	500 gallons .....	1523 kilograms.
(B) Reserved.		

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in §1300.02(b)(28) of this chapter. All such transactions, regardless of size, are subject to recordkeeping and reporting

requirements as set forth in this part and notification provisions as set forth in part 1313 of this chapter.

(1) Listed chemicals for which no thresholds have been established:

- (i) Ephedrine, its salts, optical isomers and salts of optical isomers
  - (ii) Red phosphorus
  - (iii) White phosphorus (Other names: Yellow Phosphorus)
  - (iv) Hypophosphorous acid and its salts
- (2) [Reserved]

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#### § 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

(3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the trans-

action as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in §1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(c) Each regulated person who imports or exports a tableting machine, or encapsulation machine, shall file a report (not a 486) of such importation or exportation with the Administration at the following address on or before the date of importation or exportation: Drug Enforcement Administration, P.O. Box 27284, Washington, DC 20038. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may wish to report to the Administration as far in advance as possible. A copy of the report may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media. Any tableting machine or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in §1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington, D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. A business entity which manufactures a listed chemical may elect to report separately by individual