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Title 21 – Food and Drugs

Chapter II – Drug Enforcement Administration, Department of Justice

Part 1310 – Records and Reports of Listed Chemicals and Certain Machines; Importation and Exportation of Certain Machines

Authority: 21 U.S.C. 802, 827(h), 830, 871(b) 890.
Source: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 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.

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.
8735	Benzyl cyanide	1 kilogram.
8675	Ergonovine and its salts	10 grams.

Code	Chemical	Threshold by base weight
8676	Ergotamine and its salts	20 grams.
8678	Ethylamine and its salts	1 kilogram.
6695	Hydriodic acid	1.7 kilograms (or 1 liter by volume).
8704	Isosafrole	4 kilograms.
8520	Methylamine and its salts	1 kilogram.
8502	3,4-Methylenedioxyphenyl-2-propanone	4 kilograms.
8115	N-Methylephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
8119	N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
6724	Nitroethane	2.5 kilograms.
8317	Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
8791	Phenylacetic acid, its esters, and its salts	1 kilogram.
2704	Piperidine and its salts	500 grams.
8750	Piperonal (also called heliotropine)	4 kilograms.
8328	Propionic anhydride	1 gram.
8323	Safrole	4 kilograms.

- (ii) For List I chemicals that are contained in scheduled listed chemical products as defined in § 1300.02 of this chapter, the thresholds established in paragraph (g) of this section apply only to non-retail distribution, import, and export. Sales of these products at retail are subject to the requirements of part 1314 of this chapter.

(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.

Chemical	Threshold by volume	Threshold by weight
(H) Sodium permanganate	N/A	500 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) Anhydrous Hydrogen chloride	N/A	0.0 kilograms.
(I) Sodium permanganate	N/A	55 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	50 gallons	27 kilograms.
(1) Anhydrous Hydrogen chloride		
(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.

Chemical	Threshold by volume	Threshold by weight
(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 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) Alpha-phenylacetoacetamide (APAA) and its optical isomers
- (ii) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)
- (iii) 1-boc-4-AP (*tert*-butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts.
- (iv) 1-boc-4-piperidone (*tert*-butyl 4-oxopiperidine-1-carboxylate) and its salts.
- (v) Ephedrine, its salts, optical isomers, and salts of optical isomers;
- (vi) Ergocristine and its salts
- (vii) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)
- (viii) Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)
- (ix) Iodine
- (x) 3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers
- (xi) 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers
- (xii) methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers
- (xiii) *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts
- (xiv) *N*-phenethyl-4-piperidone (NPP)
- (xv) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4-AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible.
- (xvi) P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible

- (xvii) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers
- (xviii) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers
- (xix) 4-piperidone (piperidin-4-one), its acetals, its amides, its carbamates, its salts, and salts of its acetals, its amides, and its carbamates, and any combination thereof, whenever the existence of such is possible
- (xx) Propionyl chloride
- (xxi) Red phosphorus
- (xxii) White phosphorus (Other names: Yellow Phosphorus)

(2) [Reserved]

- (h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. For purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:
 - (1) For chemical mixtures containing List I chemicals or List II chemicals other than those in paragraph (h)(2) of this section, the threshold is determined by the weight of the listed chemical in the chemical mixture.
 - (2) For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.
 - (3) If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

[54 FR 31665, Aug. 1, 1989]

Editorial Note: For FEDERAL REGISTER citations affecting § 1310.04, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.