

§ 1310.05

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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 § 1310.01(f). All such transactions, regardless of size, are subject to record-keeping and reporting requirements as set forth in this part 1310 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) [Reserved]

(2) [Reserved]

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 59 FR 51367, Oct. 11, 1994; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 60 FR 42436, Aug. 16, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 47316, Aug. 2, 2000]

§ 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 transaction 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 28346, 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 location or report as an aggregate amount for the entire business entity

provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§1310.01(f)(1)(iv) or 1310.01(f)(1)(v) except as set forth in §1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in §1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug dosage form products which contain a listed chemical.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2461, Jan. 22, 1992; 61 FR 14024, Mar. 29, 1996; 61 FR 17958, Apr. 23, 1996; 62 FR 13968, Mar. 24, 1997]

#### **§ 1310.06 Content of records and reports.**

(a) Each record required by §1310.03 shall include the following:

- (1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.
- (2) The date of the regulated transaction.