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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.

#### § 1310.13 Exemption of chemical mixtures; application.

- (a) The Administrator may, by publication of a Final Rule in the FEDERAL REGISTER, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:
  - (1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
  - (2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.
- (b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.
- (c) An application for exemption under this section shall contain the following information:
  - (1) The name, address, and registration number, if any, of the applicant;
  - (2) The date of the application;
  - (3) The exact trade name(s) of the applicant's chemical mixture and:
    - (i) If the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared; and
    - (ii) If a group of mixtures (e.g. formulations having identical function and containing the same listed chemical(s)), the information required in paragraph (c)(3)(i) of this section and a brief narrative of their use.
  - (4)
    - (i) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or
    - (ii) If a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.
  - (5)
    - (i) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and

- (ii) If a group of mixtures, how the group's properties differ from the properties of the listed chemical.
- (6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria set forth in paragraph (a) of this section.
- (7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under this section.
- (8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.
- (d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.
- (e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator will notify the applicant in writing of the acceptance or rejection of the application for filing. If the application is not accepted for filing, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is subsequently granted, the applicant shall again be notified in writing and the Administrator shall issue, and publish in the FEDERAL REGISTER, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.
- (f) The Administrator may, at any time, terminate or modify an exemption for any product pursuant to paragraph (e) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.
- (g) A manufacturer of an exempted chemical mixture shall notify DEA in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new application will be required only if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at

least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

- (h) Each manufacturer seeking exemption must apply for such an exemption. A formulation granted exemption by publication in the FEDERAL REGISTER will not be exempted for all manufacturers.
- (i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt chemical mixtures for the purposes set forth in this section and are exempted by the Administrator from application of Sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971):

**TABLE 1 TO PARAGRAPH (i)—EXEMPT CHEMICAL MIXTURES**

Manufacturer	Product name <sup>1</sup>	Form	Date
Cerilliant Corporation	1R,2S(-)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
Cerilliant Corporation	1S,2R(+)-Ephedrine-D <sub>3</sub> hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
Cerilliant Corporation	1S,2R(+)-Ephedrine-D <sub>3</sub> hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
Cerilliant Corporation	1S,2R(+)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
Cerilliant Corporation	Pseudoephedrine-D <sub>3</sub> hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/	Liquid	8/2/2007

<sup>1</sup> Designate product line if a group.

Manufacturer	Product name <sup>1</sup>	Form	Date
	dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran		
Cerilliant Corporation	R,R(-)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20) methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
Cerilliant Corporation	S,S(+)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran	Liquid	8/2/2007
E.I. DuPont deNemours & Co	RC-5156	Liquid	4/22/2005
E.I. DuPont deNemours & Co	VH-6037	Liquid	4/22/2005
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 5 mg/ml	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 2 mg/ml	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 2 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml, Stabilized, Pyridine-Based	Liquid	11/26/2018
Dr. Haces, L.L.C	PodoPhylis, Podiatric Insole	Polyurethane Iodine Insole	12/15/2021
Hawthorne Products, Inc	Sole Pack Hoof Dressing	Paste	8/14/2007

<sup>1</sup> Designate product line if a group.

<b>Manufacturer</b>	<b>Product name<sup>1</sup></b>	<b>Form</b>	<b>Date</b>
Hawthorne Products, Inc	Sole Pack Hoof Packing	Paste	8/ 14/ 2007
Lord Corporation	Chemlok TS701-52	Liquid	05/ 03/ 2018
Lord Corporation	Chemlok TS701-53	Liquid	05/ 03/ 2018
Mitsubishi Chemical Corporation	Aquamicon AKX	Liquid	04/ 08/ 2021
Mitsubishi Chemical Corporation	Aquamicon AS	Liquid	04/ 08/ 2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 1 mg	Liquid	04/ 08/ 2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 3 mg	Liquid	04/ 08/ 2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 10 mg	Liquid	04/ 08/ 2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 1 mg	Liquid	09/ 01/ 2020
Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 3 mg	Liquid	09/ 01/ 2020
Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 5 mg	Liquid	04/ 08/ 2021
Quality Assurance Service Corporation	10 to 1000 nanograms per milliliter of ephedrine in blood, serum, or urine	Liquid	9/ 26/ 2007
Quality Assurance Service Corporation	10 to 1000 nanograms per milliliter of pseudoephedrine in blood, serum, or urine	Liquid	9/ 26/ 2007

<sup>1</sup> Designate product line if a group.

<b>Manufacturer</b>	<b>Product name<sup>1</sup></b>	<b>Form</b>	<b>Date</b>
Quality Assurance Service Corporation	10 to 1000 nanograms per milliliter of phenylpropanolamine in blood, serum, or urine	Liquid	9/26/2007
Reichhold, Inc	Beckosol® 12021-00 AA-200, IA-441, P531-T	Liquid	5/05/2005
Reichhold, Inc	Urotuf® L06-30S, F78-50T	Liquid	5/05/2005
Reichhold, Inc	Beckosol AA-220	Liquid	6/14/2005
Sigma-Aldrich	Hydranal®-Composite 1	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 2	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5K	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5	Liquid	5/29/2013
Standard Homeopathic Co	Baby Cough Syrup	Liquid	9/28/2012
Standard Homeopathic Co	Defend Cough & Cold Night	Liquid	9/28/2012
Standard Homeopathic Co	Defend Cough & Cold	Liquid	9/28/2012
Standard Homeopathic Co	Diarrex	Liquid	9/28/2012
Waterbury Companies, Inc	Waterbury 332500	Liquid	4/11/2005
Waterbury	Waterbury 332762	Liquid	4/

<sup>1</sup> Designate product line if a group.

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<b>Manufacturer</b>	<b>Product name<sup>1</sup></b>	<b>Form</b>	<b>Date</b>
Companies, Inc			11/2005
Waterbury Companies, Inc	Waterbury 332400	Liquid	4/11/2005
Waterbury Companies, Inc	Waterbury 346201	Liquid	4/11/2005

<sup>1</sup> Designate product line if a group.

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[68 FR 23204, May 1, 2003, as amended at 75 FR 10681, Mar. 9, 2010; 75 FR 53869, Sept. 2, 2010; 76 FR 31830, June 2, 2011; 81 FR 97025, Dec. 30, 2016; 85 FR 4586, Jan. 27, 2020; 88 FR 72682, Oct. 23, 2023]