

## § 1310.11

Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) While a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) For a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the FEDERAL REGISTER, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) Applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

(2) There is a significant change in the data that led to the issuance of the final rule.

[60 FR 32461, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002; 75 FR 38922, July 7, 2010; 77 FR 4237, Jan. 27, 2012]

### § 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-823, 830, and 957-958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to 1310.10 affects the criminal

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liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as reinstated exempt drug products for the purposes set forth in this section:

### EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved] .....	.....	.....	

[60 FR 32462, June 22, 1995]

### § 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this section 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) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to this § 1310.12 or § 1310.13 affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts related to exempt chemical mixtures, including distribution in violation of 21 U.S.C. 842(a)(11).

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
<b>List I Chemicals</b>			
N-Acetylanthranilic acid, its salts and esters.	8522	20% by Weight .....	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Alpha-phenylacetoacetamide (APAA) and its optical isomers.	8515	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
Alpha-phenylacetoacetonitrile, and its salts, optical isomers, and salts of optical isomers. (APAAN).	8512	Not exempt at any concentration.	Chemical mixtures containing any amount of APAAN are not exempt.
Anthranilic acid, and its salts and esters.	8530	50% by Weight .....	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde .....	8256	50% by Weight or Volume.	
Benzyl cyanide .....	8570	20% by Weight or Volume.	
N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide (benzylfentanyl), including its salts.	8334	Not exempt at any concentration.	Chemical mixtures containing any amount of benzylfentanyl are not exempt.
1-boc-4-AP ( <i>tert</i> -butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts.	8336	Not exempt at any concentration.	Chemical mixtures containing any amount of 1-boc-4-AP ( <i>tert</i> -butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts are not exempt.
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Ergocristine and its salts ....	8612	Not exempt at any concentration.	Chemical mixtures containing any amount of ergocristine and its salts are not exempt.
Ergonovine and its salts ....	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.
Ergotamine and its salts ....	8676	Not exempt at any concentration.	Chemical mixtures containing amount of any ergotamine, including its salts, are not exempt.
Ethylamine and its salts .....	8678	20% by Weight or Volume	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Concentration is based on ethylamine in the mixture and not the combination of ethylamine and carrier solvent, if any.
Gamma-Butyrolactone .....	2011	70% by weight or volume.	
Hydriodic acid .....	6695	20% by Weight or Volume.	
Hypophosphorous acid and its salts.	6797	30% by weight if a solid, weight or volume if a liquid.	The weight is determined by measuring the mass of hypophosphorous acid and its salts in the mixture, the concentration limit is calculated by summing the concentrations of all forms of hypophosphorous acid and its salts in the mixture. The Administration does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. Therefore, any solution consisting of hypophosphorous acid (and its salts), dispersed in water, alcohol, or another inert carrier, is not considered a chemical mixture and is therefore subject to chemical regulatory controls at all concentrations.
Iodine .....	6699	2.2 .....	Calculated as weight/volume (w/v).
Isosafrole .....	8704	20% by Weight or Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.
methyl <i>alpha</i> -phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers.	8795	Not exempt at any concentration.	Chemical mixtures containing any amount of MAPA and its optical isomers are not exempt.
Methylamine and its salts ..	8520	20% by Weight .....	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone.	8502	20% by Weight.	

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by Weight .....	Concentration based on any combination of salts N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers.
3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers.	8535	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers.	8525	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by Weight .....	Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane .....	6724	20% by Weight or Volume.	
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by Weight .....	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
N-phenethyl-4-piperidone (NPP).	8332	Not exempt at any concentration.	Chemical mixtures containing any amount of NPP are not exempt.
Phenylacetic acid, and its salts and esters.	8791	40% by Weight .....	Concentration is based on any combination of phenylacetic acid and its salts and esters.
N-phenylpiperidin-4-amine (4-anilinopiperidine; N-phenyl-4-piperidinamine; 4-AP), including its amides, its carbamates, and its salts.	8335	Not exempt at any concentration.	Chemical mixtures containing any amount of 4-anilinopiperidine are not exempt.
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by Weight .....	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Piperidine, and its salts .....	2704	20% by Weight or Volume	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Piperonal .....	8750	20% by Weight or Volume.	
Propionic anhydride .....	8328	20% by Weight or Volume.	
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Red Phosphorus .....	6795	80% by weight.	
Safrole .....	8323	20% by Volume .....	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.
White phosphorus .....	6796	Not exempt at any concentration.	Chemical mixtures containing any amount of white phosphorus are not exempt due to concentration, unless otherwise exempted.
<b>List II Chemicals</b>			
Acetic Anhydride .....	8519	20% by Weight or Volume.	
Acetone .....	6532	35% by Weight or Volume	Exports only; Limit applies to acetone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride .....	8568	20% by Weight or Volume.	
2-butanone .....	6714	35% by Weight or Volume	Exports only; Limit applies to 2-butanone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
Ethyl ether .....	6584	35% by Weight or Volume	Exports only; Limit applies to ethyl ether or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid .....	6545	20% by Weight or Volume	Hydrogen chloride in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl isobutyl ketone .....	6715	35% by Weight or Volume	Exports only pursuant to § 1310.08; Limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate ..	6579	15% by Weight.	Sulfuric acid in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Sodium Permanganate .....	6588	15% by Weight.	
Sulfuric acid .....	6552	20% by Weight or Volume	
Toluene .....	594	35% by Weight or Volume	Exports only; Limit applies to toluene or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) Chemical mixtures that are distributed directly to an incinerator for destruction or directly to an authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700-22; persons distributing the mixture to the incinerator or recycler must maintain and make available to agents of the Administration, upon request, such documentation for a period of no less than two years.

(2) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all of the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid pro-

tective, decorative, or functional adherent film after application. Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents.

(3) Iodine products classified as iodophors that exist as an iodine complex to include poloxamer-iodine complex (*i.e.*, povidone-iodine), undecoylium chloride iodine, nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate.

(4) Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amiodarone.)

(e) The Administrator may, at any time, terminate or modify the exemption for any chemical mixture which has been granted an exemption pursuant to the concentration limits as specified in paragraph (c) of this section or pursuant to the category exemption as specified in paragraph (d) of this section. In terminating or modifying an

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exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exemption for a product or group of products for which evidence of diversion has been found, as well as 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 shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may modify any part of the criteria for exemption as specified in paragraphs (c) and (d) of this section upon evidence of diversion or attempted diversion. In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER a final order.

[68 FR 23204, May 1, 2003, as amended at 69 FR 74971, Dec. 15, 2004; 71 FR 60826, Oct. 17, 2006; 72 FR 20047, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40745, July 25, 2007; 75 FR 37306, June 29, 2010; 76 FR 17781, Mar. 31, 2011; 76 FR 31830, June 2, 2011; 82 FR 32460, July 14, 2017; 85 FR 20828, Apr. 15, 2020; 86 FR 24708, May 10, 2021; 86 FR 64366, Nov. 18, 2021; 87 FR 67552, Nov. 9, 2022]

#### § 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.