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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.

§ 1310.12 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
List I Chemicals			
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	

	DEA chemical code number	Concentration	Special conditions
Benzyl cyanide	8570	20% by Weight or Volume	
<i>N</i> -(1-benzylpiperidin-4-yl)- <i>N</i> -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

	DEA chemical code number	Concentration	Special conditions
			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	
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,	8317	0.6% by	Concentration based on any

	DEA chemical code number	Concentration	Special conditions
and salts of optical isomers		Weight	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.
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	8330	Not exempt at any concentration	Chemical mixtures containing any amount of 4-piperidone are not exempt.
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

	DEA chemical code number	Concentration	Special conditions
			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.
List II Chemicals			
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.
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.

	DEA chemical code number	Concentration	Special conditions
Potassium permanganate	6579	15% by Weight	
Sodium Permanganate	6588	15% by Weight	
Sulfuric acid	6552	20% by Weight or Volume	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.
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 protective, decorative, or functional adherent film after application. Included in this category are clear coats, top-coats, 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, polyvinyl pyrrolidone-iodine complex (*i.e.*, povidone-iodine), undecylium 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 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; 88 FR 21909, Apr. 12, 2023]