Drug Enforcement Administration, Justice

§ 1310.12

(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.

§ 1310.13 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

<table>
<thead>
<tr>
<th>DEA chemical code number</th>
<th>Concentration</th>
<th>Special conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>List I Chemicals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N-Acetylanthranilic acid, its salts and esters</td>
<td>8522</td>
<td>20% by Weight</td>
</tr>
<tr>
<td>Anthranilic acid, and its salts and esters</td>
<td>8530</td>
<td>50% by Weight</td>
</tr>
<tr>
<td>Benzaldehyde</td>
<td>8256</td>
<td>50% by Weight or Volume</td>
</tr>
<tr>
<td>Benzy1 cyanide</td>
<td>8570</td>
<td>20% by Weight or Volume</td>
</tr>
<tr>
<td>Ephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>8113</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Ergocristine and its salts</td>
<td>8612</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Ergenovine and its salts</td>
<td>8675</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Ergotamine and its salts</td>
<td>8676</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Ethylamine and its salts</td>
<td>8678</td>
<td>20% by Weight or Volume</td>
</tr>
<tr>
<td>Gamma-Butyrolactone</td>
<td>2011</td>
<td>70% by weight or volume.</td>
</tr>
<tr>
<td>Hydriodic acid</td>
<td>6695</td>
<td>20% by Weight or Volume</td>
</tr>
<tr>
<td>Hypophosphorous acid and its salts</td>
<td>6797</td>
<td>30% by weight if a solid, weight or volume if a liquid.</td>
</tr>
<tr>
<td>Iodine</td>
<td>6699</td>
<td>2.2</td>
</tr>
<tr>
<td>Isoamyl alcohol</td>
<td>8704</td>
<td>20% by Weight or Volume</td>
</tr>
<tr>
<td>Methylamine and its salts</td>
<td>8520</td>
<td>20% by Weight</td>
</tr>
<tr>
<td>3,4-Methyleneoxydiphenyl-2-propanone</td>
<td>8502</td>
<td>20% by Weight</td>
</tr>
<tr>
<td>N-Methylphendrine, its salts, optical isomers, and salts of optical isomers</td>
<td>8115</td>
<td>0.1% by Weight</td>
</tr>
<tr>
<td>N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>8119</td>
<td>0.1% by Weight</td>
</tr>
<tr>
<td>Nitroethane</td>
<td>8317</td>
<td>0.6% by Weight</td>
</tr>
<tr>
<td>Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>8332</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers</td>
<td>8791</td>
<td>40% by Weight</td>
</tr>
<tr>
<td>N-phenethyl-4-piperidone (NPP)</td>
<td>1225</td>
<td>0.6% by Weight</td>
</tr>
<tr>
<td>Phenethylacetic acid, and its salts and esters</td>
<td>8530</td>
<td>50% by Weight</td>
</tr>
<tr>
<td>Phenethylacetic acid, and its salts and esters</td>
<td>8530</td>
<td>50% by Weight</td>
</tr>
<tr>
<td>Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers</td>
<td>8113</td>
<td>Not exempt at any concentration</td>
</tr>
<tr>
<td>Piperidine, and its salts</td>
<td>2704</td>
<td>20% by Weight or Volume</td>
</tr>
</tbody>
</table>
TABLE OF CONCENTRATION LIMITS—Continued

<table>
<thead>
<tr>
<th>DEA chemical code number</th>
<th>Concentration</th>
<th>Special conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piperonal ..................</td>
<td>8750 20% by Weight or Volume.</td>
<td>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.</td>
</tr>
<tr>
<td>Propionic anhydride .......</td>
<td>8328 20% by Weight or Volume.</td>
<td>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.</td>
</tr>
<tr>
<td>Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.</td>
<td>8112 Not exempt at any concentration.</td>
<td></td>
</tr>
<tr>
<td>Red Phosphorus .............</td>
<td>6795 80% by weight.</td>
<td>Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.</td>
</tr>
<tr>
<td>Safrole ........................</td>
<td>8323 20% by Volume ..........</td>
<td>Chemical mixtures containing any amount of white phosphorus are not exempt due to concentration, unless otherwise exempted.</td>
</tr>
<tr>
<td>White phosphorus ...........</td>
<td>6796 Not exempt at any concentration.</td>
<td></td>
</tr>
<tr>
<td><strong>List II Chemicals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetic Anhydride ..........</td>
<td>8519 20% by Weight or Volume.</td>
<td>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.</td>
</tr>
<tr>
<td>Acetone ........................</td>
<td>6532 35% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Benzyl chloride ..................</td>
<td>8568 20% by Weight or Volume.</td>
<td>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.</td>
</tr>
<tr>
<td>2-butanone .....................</td>
<td>6714 35% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Ethyl ether ........................</td>
<td>6584 35% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Hydrochloric acid ...........</td>
<td>6545 20% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Methyl isobutyl ketone ......</td>
<td>6715 35% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Potassium permanganate .....</td>
<td>6579 15% by weight.</td>
<td>Chemically produced 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.</td>
</tr>
<tr>
<td>Sodium Permanganate ......</td>
<td>6588 15% by Weight.</td>
<td>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.</td>
</tr>
<tr>
<td>Sulfuric acid .................</td>
<td>6552 20% by Weight or Volume</td>
<td>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.</td>
</tr>
<tr>
<td>Toluene ..........................</td>
<td>594 35% by Weight or Volume</td>
<td>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.</td>
</tr>
</tbody>
</table>

(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 generally exempt from the provisions of the Controlled Substances Act.
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 adhesive 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, 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 as specified in paragraph (d) of this section. 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 or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER a final order.

§ 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 Office of Diversion Control, 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: