

Reference	Controlled Substance	Exempted from	Requirement/s	
Sec 4 (2)(b)	<b>BUPRENORPHINE</b> patch	Special Prescription Form for Dangerous Drugs (DD)	Ordinary Rx in triplicate copies with S2	
Sec 4(4)(a),	All oral forms of FDA-registered drug preparations in <b>PHILIPPINE SCHEDULES 4 AND 5</b>	Special Prescription Form for DD and Local order permit for transactions between a wholesale distributor and retail drugstore, and hospital pharmacy.	Ordinary Rx in triplicate copies	
Sec 4(4)(b)	<b>In vitro diagnostic reagents, buffers and analytical standards and test kits containing dangerous drug for diagnostic test</b> to determine drugs in body fluids or nature of disease	All regulatory requirements under this regulation except ...	...registration and licensing of importer	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4(5)	FDA-registered pharmaceutical oral drug preparations containing <b>ERGOMETRINE/ERGONOVINE, ERGOTAMINE, NOREPHEDRINE</b> and their salts, and compounded galenical preparations (solutions) containing <b>POTASSIUM PERMANGANATE</b> intended as disinfectant, antibacterial and antifungal agents	All regulatory requirements under this regulation except ...	...registration and licensing of importer, exporter and manufacturer.  ...import permit is required if importation of finished product <u>exceeds</u> the following equivalent quantities of:	Importation/exportation shall be reported to PDEA not later than five (5) working days before date of importation / exportation of the shipment.

			<ul style="list-style-type: none"> <li>- 0.010g ergometrine / ergonovine,</li> <li>- 0.020g ergotamine,</li> <li>- 2.5Kg norephedrine and</li> <li>- 1kg potassium permanganate per importation</li> </ul>	
Sec 4 (6), Sec 4(6)(a)	Completely formulated paints that contain all paint or coating components for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. Included but not exclusive in this category are clear coats, top – coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film – forming agents, epoxies, vinyl, lacquer, contact cements, waxes, cleaning agents that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	<p>...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.</p> <p><b>Toluene is banned in spray paints and glue at concentration equal to or higher than 0.1% by weight that are intended for sale to the general public. Such is not banned if intended for industrial use.</b></p>	NOTE: Manufacturers, importers and distributors of spray paints and glues containing equal to or higher than 0.1% by weight of Toluene that are intended for sale to the general public shall be given until <b>March 12, 2016</b> to dispose/ retrieve/recall said products from the market. Thereafter, all remaining stocks shall be seized and subject handlers shall be sanctioned accordingly.

Sec 4 (6), Sec 4 (6)(b)	Silicone product that is a sealant, adhesive or coating or other products containing <b>ACETIC ANHYDRIDE</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4 (6), Sec 4 (6)(c)	Perfume and soya sauce or other products containing <b>ANTHRANILIC ACID</b> that is intended for sale to the general public.	All regulatory requirements under this	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition	



Sec 4(7), Sec 4 (7)(a)	Chemical mixtures containing <b>≤30% HYDROCHLORIC ACID.</b>	...	...registration / licensing of importer.	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4 (6), Sec 4 (6)(f)	Lacquer, varnishes, paint remover, glues, polysterene cement, cleaning agent, dry erase markers or other household products containing <b>METHYL ETHYL KETONE</b> that is intended for sale to the general public	All regulatory requirements under this regulation except	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(a)	Chemical mixtures containing <b>≤35% METHYL ETHYL KETONE</b> (Note: aggregate sum rule applies; please refer to Clarification No. 4)	...	...registration / licensing of importer.	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4 (6), Sec 4 (6)(g)	Perfume, bird and insect repellents or other products containing <b>PHENYLACETIC ACID</b> that is intended for sale to the general public.	All regulatory requirements under this regulation	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(c)	Preparations or mixtures of fragrances or flavorings containing <b>≤40% PHENYLACETIC ACID</b> intended to be used in a food, drug, cosmetic or household product	except...	...registration / licensing of importer.	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4 (6), Sec 4 (6)(h)	Rubber vulcanization accelerator or other products containing <b>PIPERIDINE</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(c)	Chemical mixtures of fragrances or flavorings containing <b>≤35% PIPERIDINE</b> intended to be used in a food, drug, cosmetic or household product.	...	...registration / licensing of importer	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.

Sec 4 (6), Sec 4 (6)(i)	Synthetic vanilla flavor, candies, and perfume or other products containing <b>PIPERONAL</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4 (6), Sec 4 (6)(j)	Drain and metal cleaners, anti-rust compounds, lead-acid (e.g. car) batteries containing less than 51% sulfuric or other products or compounds containing <b>SULFURIC ACID</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(a)	Chemical mixtures containing <b>≤30% SULFURIC ACID.</b>		...registration / licensing of importer.	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4 (6), Sec 4 (6)(k)	Polystyrene kits, coatings for floors and furniture, artificial sports tracks, ski suits and waterproof leisure wear, nail cosmetics, adhesive remover intended for use on humans or animals, adhesive used on humans and animals, tape, contact paper, wallpaper, shelf liners, or any other product with an adhesive incorporated onto or in an inert substrate, spray paints and glue at concentrations less than 0.1 per cent by weight or other articles or products containing <b>TOLUENE</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(a)	Chemical mixtures containing <b>≤35% TOLUENE.</b> (Note: aggregate sum rule applies; please refer to Clarification No. 4)		...registration / licensing of importer	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.

Sec 4 (6), Sec 4 (6)(l)	Lithium – thionyl chloride batteries or other articles or products containing <b>THIONYL CHLORIDE</b> that is intended for sale to the general public.	All regulatory requirements under this regulation except ...	...registration / licensing of manufacturer, and recording and reporting of raw mat acquisition and usage.	
Sec 4(7), Sec 4 (7)(a)	Chemical mixtures containing <b>≤35% ETHYL ETHER</b> . (Note: aggregate sum rule applies; please refer to Clarification No. 4)	All regulatory requirements under this regulation except ...	...registration / licensing of importer	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.
Sec 4(7), Sec 4 (7)(b)	Chemical mixtures containing <b>≤15% POTASSIUM PERMANGANATE</b> .	All regulatory requirements under this regulation except ...	...registration / licensing of importer	Importation shall be reported to PDEA within five (5) working days upon arrival of the shipment at port of entry.

**Clarifications:**

1. The matrix was created for the purpose of clarifying licensing and permit requirements found in Section 4 (Preparations) in relation to Annex “D” of Board Regulation 1, Series of 2014.

2. Section 4 (6) (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), and (l) pertain to **FINISHED PRODUCTS REGARDLESS of its concentration specified in the “Table of Concentration Limits” (Annex “D”) that are intended for sale to the general public ARE EXEMPTED from All regulatory requirements; EXCEPT if the importer is a manufacturer, thus the company shall secure a license as compounder/manufacturer (P5C) from PDEA and must comply with the recording and reporting requirements for the raw materials and its usage. . General Public refers to all buyers of the said product(s) domestically.**
3. Section 4 (7) (a), (b) and (c) refer to **CHEMICAL MIXTURES or ARTICLES / PRODUCTS** not covered under Sec. 4(6) (a to l) **that are not intended for sale to the general public. Importation of chemical mixtures in concentrations equal to or less than those specified in the “Table of Concentration Limits” are automatically exempted from specified control measures EXCLUDING registration of license of importer. With respect to importation of chemical mixtures exceeding the percentage thresholds provided in the matrix, the importer with valid PDEA License may either apply for a Special Permit with the PDEA OR a Certificate of Exemption with the Dangerous Drugs Board** prior to importation. Importation made shall be reported to PDEA within five (5) working days upon arrival of the shipment.

With regard to the **aggregate sum rule**, the **total percentage content of all controlled chemicals present in the chemical mixture shall not exceed the given concentration weight limit provided in Annex “D”, or in this matrix, the given percentage weight per controlled substance in a chemical mixture.**

4. **The Dangerous Drugs Board shall issue a Certificate of Exemption upon request by the company.**
5. **Toluene is banned in spray paints and glues at concentrations equal to or higher 0.1% by weight that is intended for sale to the general public. Manufacturers, importers and distributors of such products shall be given one (1) year from the effectivity of the Regulation (or until March 12, 2016) to dispose of and retrieve/recall said products from the market.**
6. All companies are given one (1) year from the effectivity of the Regulation **(or until March 12, 2016)** to comply with the new storage requirements.
7. **All PDEA S- and P- License holders shall be allowed to renew their respective licenses without payment of back accounts and penalties due to non – submission of notice of discontinuance or retirement of license to PDEA until September 15, 2015.**
8. All concerned transporters/haulers/carriers of bulk controlled substance are given one (1) year from the effectivity of the Regulation **(until March 12, 2016)** to comply with the accreditation requirements of PDEA.

9. **All lead acid batteries** containing less than 51% Sulfuric acid that are intended for sale to general public are automatically exempt from all regulatory requirements except manufacturers ( Sec. 4(6)(j).
10. **All batteries containing Thionyl Chloride** that are intended for sale to general public are automatically exempt from all regulatory requirements except manufacturers ( Sec. 4(6)(l).
11. All finished products (Section 4(6) ) and/or Chemical mixtures **purchased domestically** are exempted from acquiring P-3 License (end-user).