



UNITED NATIONS

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE
CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE
AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS
AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

FRANCE :

COMMUNICATED BY THE GOVERNMENT OF
FRANCE .

NOTE BY THE SECRETARY-GENERAL

In accordance with Article 21 of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol of 11 December 1946, the Secretary-General has the honour to communicate the following legislative text.

New York, 1952

POISONOUS SUBSTANCES	PHARMACEUTICAL FORMS	NOT DIVIDED	DIVIDED	MAXIMUM
		INTO DOSES	INTO DOSES	WEIGHT OF
		Maximum	Maximum	SUBSTANCES
		percentage	concentration	sold to
		concentration	per dose	the public
		(by weight)	(in grammes)	(in grammes)
Methylbutylmalonate; Isopropylallylmalonate; Isobutylallylmalonate; Ethylmethylbutylmalonate; Ethylisoamylmalonate; Phenylethylmalonate;	tablets coated with a substance designed to delay digestion (gluten or gum) (should meet all three requirements).	5	0.01	0.50
Cyclopentylethylmalonate; Ethylcyclohexenylmalonate; N-methylcyclohexenylmalonate and other malonate derivatives not designated.	2. Bougies, pencils, capsules, suppositories 3. All other forms	0	0	0
Opiated mercury chloride pills (Dupuytren)				25 pills
Opiated cynoglossum pills (and mass for)			i.e.	50 pills
Opiated mercury iodide pills (Ricord)				10 pills
Opiated ipeca powder	All forms		0.10	4
Codeine syrup				250
Codethyline syrup				250
Morphine syrup				50
Opium syrup				50

ANNEX

In accordance with the foregoing schedules, preparations entered in the Codex and subject to the regulations governing poisonous substances, shall enjoy the following exemptions:

PREPARATIONS	NUMBER	WEIGHT IN GRAMMES
Officinal paste of balm of tolu and codeine		800
Terpine and codeine pills	40	
Coca wine		1,000

Original: French

Extracts from the *Journal officiel* of the French Republic
for 8 and 9 March 1951

MINISTRY OF HEALTH AND POPULATION

REGULATIONS GOVERNING MEDICATED PREPARATIONS CONTAINING POISONOUS SUBSTANCES

Order of 24 February 1951 to introduce regulations
governing medicated preparations containing poisonous substances

The Minister of Public Health and Population,

Having considered the Decree of 19 November 1948 to introduce public administrative regulations to give effect to the amended Act of 19 July 1845 on trade in poisonous substances, and in particular article 19 of the said Decree

HEREBY ORDERS:

Article 1. Subject always to the requirements of the following articles, the provisions of title II of the Decree of 19 November 1948 shall not apply to medicated preparations containing poisonous substances in quantities and concentrations equal to or less than those indicated in the Schedules annexed to this Order, and made up in the forms described in the said Schedules.

Substances not listed in the schedules annexed hereto shall not be exempted in any way.

Article 2. In whatever form they may be made up, preparations containing substances listed in Schedules A and C shall be exempt only in so far as the measure or weight of the poisonous substance on sale to the public is equal to or less than that laid down in the Schedules annexed hereto.

These preparations shall also meet one of the two other requirements laid down in the Schedules, according to whether or not they are divided into doses.

Article 3. In addition to the provisions laid down in article 2 for substances listed in Schedules A and C, preparations containing substances listed in Schedule B (narcotic drugs) shall, in all cases, meet the requirements as to concentration laid down in the Schedules annexed hereto.

Article 4. The exemptions provided for in this Order shall not apply to injectable solutions, except where expressly stated in the Schedules annexed hereto.

Article 5. In accordance with the provisions of article 19 of the Decree of 19 November 1948, records relating to the manufacture of exempted preparations containing substances listed in Schedule B (narcotic drugs) shall be kept as prescribed in articles 43 and 58 of the said Decree.

Article 6. The exemptions made for alkaloids shall extend to those of their salts which are listed in the schedule of poisonous substances, in proportion to the quantity of the basic alkaloid from which they are derived.

Article 7. This Order shall annul and replace the Order of 11 January 1949.

Article 8. The Chief of the Central Pharmacy Service shall be responsible for administering this Order which shall be published in the *Journal officiel* of the French Republic.

Done at Paris, 24 February 1951

(Supplement to the *Journal officiel*)

(signed)

Technical Adviser
for the Minister, by delegation

SCHEDULE A

<i>POISONOUS SUBSTANCES</i>	<i>PHARMACEUTICAL FORMS</i>	<i>NOT DIVIDED INTO DOSES Maximum percentage concentration (by weight)</i>	<i>DIVIDED INTO DOSES Maximum concentration per dose (in grammes)</i>	<i>MAXIMUM WEIGHT OF SUBSTANCES sold to the public (in grammes)</i>
Apomorphine and its salts	all forms	0.01	0.001	0.01
Codeine and its salts	all forms	0.20	0.04	0.40
Cotamine and its salts	for dermal application	2		1.20
	Other forms	1	0.02	0.40
Ethylmorphine and its salts	Eyewashes and eye salve	1		0.10
	Other forms	0.20	0.03	0.30
Morpholyethyl morphine	all forms	0.40	0.08	0.80
Narceine and its salts	all forms	0.20	0.01	0.20
Papaverine and its salts	Rougies, pencils, capsules, suppositories		0.04	0.50
	Other forms	1	0.03	0.60
Poppy (dried heads)	Species	33	3	15
Tincture of coca	all forms	60		125

SCHEDULE B

POISONOUS SUBSTANCES	PHARMACEUTICAL FORMS	NOT DIVIDED	DIVIDED	MAXIMUM
		INTO DOSES	INTO DOSES	WEIGHT OF
		Maximum percentage concentration (by weight)	Maximum concentration per dose (in grammes)	SUBSTANCES sold to the public (in grammes)
Coca (leaves)	all forms	6	3	60
Coca (fluid extract)	all forms	6	3	60
Cocaine and its salts	Bougies, pencils, capsules, suppositories	0.10	0.01	0.10
	For dermal application	0.10		0.50
	Other forms	0.10	0.001	0.05
Ethylether of methyl- phenylpiperidine- carbonic acid and its salts (pethidine)	For dermal application	2		1
	For oral administration	2	0.025	0.125
	Other forms	0	0	0
Morphine and its salts	For dermal application	0.20		0.10
	For oral administration	0.20	0.005	0.025
	Other forms	0	0	0
Opium (extract)	For dermal application	1		0.50
	Other forms (finished supposi- tories must have a minimum weight of 3 grammes)	1	0.025	0.125
Opium (powder)	For dermal application	2		1
	Other forms (finished supposi- tories must have a minimum weight of 3 grammes)	2	0.05	0.25
English Black drops	For dermal application	4		2
	Other forms	4	0.10	0.50

SCHEDULE B (cont'd)

POISONOUS SUBSTANCES	PHARMACEUTICAL FORMS	NOT DIVIDED	DIVIDED	MAXIMUM
		INTO DOSES	INTO DOSES	WEIGHT OF
		Maximum	Maximum	SUBSTANCES
		percentage	concentration	sold to
		concentration	per dose	the public
		(by weight)	(in grammes)	(in grammes)
Tincture of Opium	For dermal application	20		10
	Other forms	20	0.50	2.50
Poppy extract (10 per cent morphine)	For dermal application	2		1
	Other forms	2	0.05	0.25
Laudanum	All forms	0	0	0

Paregoric elixir	All forms			25
Extract of opium plaster	Plaster			50
<p>Malonate (derivates of and salts). For all compounds of more than one malonate derivatives, the maximum quantities of each should be decreased in proportion to the number of substances in the compound: i.e., 50 per cent if there are two, 33 per cent if there are three, etc. :</p>				
1. Barbital: Diethylmalonate; Dipropylmalonate; Methylphenylmalonate.	1. In association with other medicated substances: tablets coated with a substance intended to delay digestion (gluten or gum) (should meet all three requirements).	10	0.05	1
	2. Bougies, pencils, capsules, suppositories.		0.50	5
	3. All other forms.	0	0	0
2. Phenobarbital group: Diallylmalonate;	1. In association with other medicated substances:			