

Regulation on drug precursors

Explanatory note to Regulation (EU) No 1258/2013 amending Regulation (EC) No 273/2004 on drug precursors and Regulation (EU) No 1259/2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Dear Sir/Madam,

The FAMHP wishes to provide you with more precise details on the practical implementation of two new European Regulations (No 1258/2013 and No 1259/2013 laying down rules for the monitoring of intra- and extra-Community trade of scheduled substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances in order to prevent the diversion of such substances).

With respect to the **export** of **Category 4** substances (medicinal products and veterinary medicinal products containing ephedrine or pseudoephedrine, or its salts **to third countries (outside the European Union)**), the export licence application form must be filled out as follows:

- Points 2 to 4 and point 21 are reserved for the competent authority.
- 14a/b: Scheduled substance:
 1. The name of the Category 4 substance.
 2. Ephedrine or pseudoephedrine concentration: the quantity of ephedrine or pseudoephedrine per drug unit (e.g. mg/capsule, mg/ml).
 3. The total quantity of the substance for export: the number of capsules, ml, etc. for export (ex. number of capsules in each box and total ml per bottle and total number of bottles).
 4. The total quantity of ephedrine or pseudoephedrine in the form of an **anhydrous base** for export (see calculation below).

Example

*Name, 120 mg pseudoephedrine sulphate/capsule, 6 capsules/box, 15500 boxes
0.12 g pseudoephedrine sulphate x 0.77 (sulphate conversion factor) x 6 x 15500
= 8593.2 g of pseudoephedrine sulphate, anhydrous base for export*

The table below sets out **the conversion factors** to convert the ephedrine or pseudoephedrine

bases or its salts into an anhydrous base:

Substance	Base or salt	Conversion to an anhydrous base
Ephedrine	Hemihydrate base (0.5 H ₂ O)	0.95
	Hydrochloride	0.82
	Nitrate	0.72
	sulphate	0.77
Pseudoephedrine	Hydrochloride	0.82
	sulphate	0.77

- 15a/b: NC Code for the Category 4 substance.

Substances for human or veterinary use containing ephedrine (or its salts)	NC code: 3003 41 20 (Neither presented in the form of doses nor packaged for retail)
	NC code: 3004 41 20 (presented in the form of doses or packaged for retail)
Substances for human or veterinary use containing pseudoephedrine (or its salts)	NC code: 3003 42 30 (Neither presented in the form of doses nor packaged for retail)
	NC code: 3004 402 30 (presented in the form of doses or packaged for retail)

- 16a/b: Net weight of the substance: i.e. the total net weight of the tablets or liquid for export, **excluding packaging**, expressed in **kg**.
- 17a/b: % **ephedrine or pseudoephedrine** (anhydrous base) in the total **net weight of the substance**.

This percentage allows calculation of the quantity of ephedrine or pseudoephedrine contained in the net weight of the substance by multiplying the net weight by this percentage.

Example

Where a capsule weighs 1 g and the concentration of pseudoephedrine sulphate is 0.12 g/capsule and there are 1000 capsules for export:

1000 g of the drug x 0.12 g of pseudoephedrine sulphate/g of the substance.

= 120 g of pseudoephedrine sulphate for export

= 12 % of the net weight of the substance for export

To convert the sulphate form to an anhydrous base, multiply by 0.77 (conversion factor):

120 g x 0.77 = 92.4 g pseudoephedrine (anhydrous base)

The percentage to be noted in section **17a/b** is:

12 % x 0.77 = 9.24 %

1000 g (net weight of the substance) x 9.24 % = 92.4 g anhydrous pseudoephedrine

- Points 20 to 22 are reserved for the customs authorities.

The full text of the Regulations is available on the FAMHP website in the legislations on precursors section:
http://www.fagg-afmps.be/fr/humain/produits_particuliers/subst_specialement_reglementees/precurseurs

If you have any questions, please contact:

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Yours faithfully,

X. De Cuyper
General Administrator