

Guidance for completing import permit applications for precursor substances

Version 1.3, October 2022

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Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
8 December 2016	1.0	Original publication	ODC
26 July 2017	1.1	Updated contact details	ODC
8 August 2022	1.2	Updated Department name	ODC
October 2022	1.3	Updated information	ODC

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Introduction

The following precursor substances that have the potential to be used in the manufacture of illicit drugs are controlled under Regulation 5 of the <u>Customs (Prohibited Imports) Regulations 1956</u>.

- Ephedrine
- Ergometrine
- Ergotamine
- 1-Phenyl-2-propanone
- Pseudoephedrine
- Phenylacetic acid
- N-acetylanthranilic acid and anthranilic acid
- Safrole and oil of sassafras
- Isosafrole
- Piperonal
- Phenylpropanolamine (norephedrine)
- Lysergic acid
- 3,4-methylenedioxyphenyl-2-propanone
- Gamma-butyrolactone
- 4-anilino-N-phenethylpiperidine (ANPP)
- 3,4-MDP-2-P methyl glycidate
- 3 4-MDP-2-P methyl glycidic acid
- Methyl alpha-phenylacetoacetate (MAPA)
- N-Phenethyl-4-piperidinone (NPP)
- alpha-Phenylacetoacetamide (APAA)
- alpha-Phenylacetoacetonitrile (APAAN)
- and all salts and esters of these substances

The importation of these substances is prohibited unless the importer holds a licence and permit issued under the Customs (Prohibited Imports) Regulations 1956. A permit is required for each consignment that is imported whereas licenses are issued annually. Information on <u>obtaining a licence</u> is available separately from the Office of Drug Control (ODC) website.

To apply for a permit to import precursor substances the application form titled '<u>Application for a permit to import precursor substances</u>' must be submitted to NCS. The guidance provided here will assist you in completing and submitting the application form.

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Completing the form

The table below will assist you in identifying the required information for completing the permit application form.

Part of application form	Explanation of required information
Check box for 'Raw Material' or 'Finished Goods'	

Check one box to indicate whether the precursor substance you are proposing to import is a raw material (for example a bulk substance for further manufacturing) or a finished good (for example a pharmaceutical preparation).

1. Importer information	
Licence holder's name	Permits to import controlled substances can only be issued to importers who hold a licence to import substances covered by regulation 5 of the Customs (Prohibited Imports) Regulations 1956. State the name of the licence holder.
Company name	State your company's name
Import licence number	State your import licence number, which can be found on your licence issued by the NCS.
Approximate date of import	Indicate the expected import date for the consignment if the import permit is issued. If the exact date is not known, provide the approximate time period (e.g. Oct 2022).
Company address	State the physical address to be displayed on the import permit
Postal address	State the postal address to which you would like the export permit sent. Permits will be sent by standard mail unless an express post envelope accompanies the application.
2. Exporter Information	
Overseas exporter's full name	State the full name of the overseas exporter
Overseas exporter's address	State the physical address of the overseas exporter to be displayed on the import permit
3. Substance Details	
Substance name	Provide the name of the precursor chemical (e.g. ephedrine HCl)

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Part of application form	Explanation of required information
Trade name	If a finished good, provide trade name of the goods
Concentration/Strength	Indicate the concentration/strength of the controlled substance:
	• Raw Material: for assayable substances include the assay amount i.e. 98%
	 Finished goods: show the amount of controlled substance in the preparation, for example mg/mL for liquids or mg per tablet for tablet products. The concentration should be in metric units.
Form of substance	Indicate the form of the finished goods, for example tablets, capsules, vials, ampoules etc.
Pack type and size	Provide details on the pack type and the size
	• Raw material: for example, 25 kg drum
	• Finished goods: for example; 24 tablet blister pack; 100 mL bottle; box of 100 tablets; box of 6 x 2 mL ampoules.
Total number of packs in shipment	Specify the total number of packs (as defined above) that make up the proposed shipment. For example 25 packs of 24 tablets; 100 bottles of 100 mL; 1000 boxes of 100 tablets, 250 boxes of ampoules.
End user declaration	For precursor substances that are raw materials you should attach an End User Declaration (EUD) from yourself as the importer and from customers who you intend to supply the consignment to.
	Importer EUD
	The EUD from the importer must describe what the substance will be used for, including supply to nominated customers where relevant.
	Customer EUD
	Where you have nominated that you will supply imported materials to specific customers you should also attach signed EUD's from those customers. All customer EUD's must be signed by the proposed customer, state what the goods will be used for and that the goods will not be used for the production of illicit drug substances.

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Part of application form	Explanation of required information
ARTG / APVMA / Laboratory Use / SAS Sponsor / CTN	The ARTG No. (Australian Register of Therapeutic Goods) refers to the number allocated to all TGA-approved therapeutic goods. The ARTG number must be provided for all imported finished goods that have a therapeutic claim. This is not applicable to raw materials or non-therapeutic goods.
	The APVMA Product No. (Australian Pesticides and Veterinary Medicines Authority) applies to all approved pesticides and veterinary products. If the APVMA number is not available a copy of the APVMA permission or permit must be provided. This is not applicable to raw materials.

Laboratory Use – Material that will be used for laboratory or research purposes only.

SAS Sponsor - A commercial quantity of an unregistered therapeutic good that is to be used in accordance with the Special Access Scheme – Sponsors Exemption.

The **CTN** refers to the clinical trial notification or **CTX** (clinical trial exemption).

4. Declaration and Consent

Make sure you read and understand the declaration and consent. Sign the application form. Complete the contact details of the person signing the form. The form must be signed by the licence holder or a person that the licence holder has authorised in writing to make applications under the licence.

Submitting an application

You can submit your application in the following ways:

Mail	Narcotics Control Section Office of Drug Control GPO Box 9848 Canberra ACT 2601
Email	NCS@health.gov.au

NCS endeavours to process applications for permits within 20 business days from the date of receipt of a correctly completed application and requisite supporting documentation. While a very high proportion of applications are processed within 10 days, there will be times where high demand for permits may result in slightly longer processing times. Application forms that contain incomplete or incorrect information will be returned to you for amendment, resulting in delays in processing.

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It is the responsibility of the importer to ensure that the triplicate copy of the permit is completed at the time of importation and the hardcopy returned to NCS.

It is responsibility of the importer to return the endorsed triplicate copy to NCS no later than **14 days** after the importation has occurred. Failure to comply with this condition may result in cancellation of import licenses.

Unused or **expired** permits must be returned within **14 Days**.

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