

## Use of drug precursor chemicals in the University

European Union legislation seeks to prevent the illicit use of drug precursors (EC No 273/2004). The Regulations are concerned with control and monitoring of certain substances frequently used for the illicit manufacture of narcotic or psychotropic substances with a view to preventing their diversion. Three categories of substances are defined. The impact of these Regulations for the University is that a license is now required for the use of [Category 1](#) substances, and for both [Category 1](#) and [Category 2](#) substances a customer [declaration](#) must be provided to the supplier.

The licenses are issued by the Home Office and until the end of 2010 a single licence for each campus using these substances was accepted and this was arranged by the Safety Office. However, from 1st January 2011 the licensing regime was changed such that each area will require its own license for any Category 1 drug precursors. Additionally the licences now attract fees with the charges for 1st January 2011 being (as of February 2014):

- New application for a category 1 licence = £3,655
- Annual renewal of an existing licence:
  - category 1 licence, where no compliance visit is required = £326
  - category 1 licence, where a compliance visit is necessary = £1,371

For further information on fees and to obtain the application form and guidance see: <http://www.homeoffice.gov.uk/drugs/licensing/precursors-chemical-licensing/domestic-licensing/>

A license application (new or renewal) should be submitted on the basis of one for each **Responsible Person's** jurisdiction. As a guide to identifying who should be the Responsible Person and how many might be required the following considerations are based on the key points from the regulations and licence conditions:

- The locally responsible person should normally be the Principal Investigator with overall responsibility for the work using these substances and therefore able to closely supervise their use. Where substances are used in a number of research groups it might be appropriate to appoint a local responsible person for each group.
- The duties of the locally responsible person are as follows:
  - To supervise the use of category one substances to ensure compliance with the regulations.
  - To ensure that accurate records are maintained for the acquisition use and disposal of category one substances, and to provide reports of these if requested to submit returns to the Home Office.
  - To ensure that category one substances are kept in a secure location (e.g. locked cupboard) to which access is restricted to authorised persons.

- To notify promptly the Head of School and the Safety Office in the event of any theft, unexplained loss or other suspicious transactions being identified.

The Responsible Person will need to be notified to the Home Office as part of the license application. This person will be legally responsible for ensuring the security and correct use of the substances and will require enhanced CRB checking (as will their Guarantor, usually the Head of School) as part of the increased security provision. **To initiate CRB checking phone 0870 850 2516 to apply to be checked and get the relevant application forms.** Further information can be found at: <http://www.capitarvs.co.uk/> (Capita Recruitment Vetting Service is contracted to the Drugs Licencing and Compliance Unit to supply a CRB checking service)

The regulations and other useful information can be found on the Home Office website at: <http://www.homeoffice.gov.uk/drugs/licensing/>

### **Category 1 substances**

Category 1 substances include the following (in pure form or mixtures):

- 1-phenyl-2-propanone
- N-acetylanthranilic acid
- Isosafrol (cis+trans)
- 3,4-methylenedioxyphenyl-propan-2-one
- Piperonal
- Safrole
- Ephedrine
- Pseudoephedrine
- Norephedrine
- Ergometrine
- Ergotamine
- Lysergic acid
- Alpha phenylacetoacetonitrile (better known as APAAN)

Please see the full [list of regulated substances](#) with their Combined Nomenclature Code (the CN Code is needed for applications and declarations) and CAS number.

### **Organisation and Responsibilities**

1. The Head of any School working with one or more Schedule One substances shall appoint one or more Responsible Persons to ensure that use of these substances takes place in compliance with the Regulations.
2. The Responsible Person should normally be the Principal Investigator with overall responsibility for the work using these substances and therefore able to closely supervise their use. Where substances are used in a number of research groups it might be appropriate to appoint a local responsible person for each group.
3. The duties of the locally responsible person are as follows:
  - To supervise the use of category one substances to ensure compliance with the regulations.

- To ensure that accurate records are maintained for the acquisition use and disposal of category one substances, and to provide reports of these to the Safety Office as requested in order to submit returns to the Home Office.
  - To ensure that category one substances are kept in a secure location (e.g. locked cupboard) to which access is restricted to authorised persons.
  - To notify promptly the Head of School and the Safety Office in the event of any theft, unexplained loss or other suspicious transactions being identified.
4. The Head of School shall ensure that the Safety Office is notified of any applications for category 1 licences or changes in the use of such substances.

### **Declaration of Specific Use**

1. Suppliers of Category 1 substances will require customers to complete a *Declaration of Specific Uses Form* (available from the Home Office website at: <http://www.homeoffice.gov.uk/drugs/licensing/precursors-chemical-licensing/domestic-licensing/>).
2. Schools should keep copies of *Declaration of Specific Uses Forms* for at least 3 years after the end of the calendar year in which the final disposal of the consignments to which they relate occurred. A copy must also be sent to the Safety Office.

### **Security and Accounting of Category 1 Substances**

1. Schools must set up a simple record keeping system which should include:
  - Supplier and date of supply of Category 1 substances;
  - Nature of chemical or preparation;
  - Concentration and amount of substance;
  - Where it will be kept and who by;
  - Date and mode of eventual disposal.

A [model form](#) has been produced and should be used for this.

2. Category 1 substances must be kept securely (e.g. under lock and key when not being used). This also applies, as far as is practicable, to solutions/preparations prepared from the original consignment that could be used for illicit drug manufacture. Preparations or mixtures that are compounded in a manner that they could not be easily used or extracted are exempt.
3. Advice on methods of safe keeping can be obtained from the Security Office.
4. Schools should ensure that only authorised persons have access to Category 1 substances. Departments must inform the Safety Office forthwith if there is a theft or unexplained loss of Category 1 substances.
5. Departments must also inform the Safety Office if they wish to supply Category 1 substances to parties outside the University. This will almost certainly constitute "trade" and additional Regulations could apply.

### **Category 2 substances**

Category 2 substances include the following:

### Category 2A:

- Acetic anhydride

### Category 2B:

- Phenylacetic acid
- Anthranilic acid
- Piperidine
- Potassium permanganate.

1. Category 2B substances will not require a licence to be supplied with these substances but suppliers will require customers to complete a Declaration of Specific Uses Form. [N.B. when completing the declaration form the section requiring a registration/licence number should be left blank as this only applies to Category 1 substances.] However Category 2A substances likely to be used in excess of 100 litres/ annum (calendar year) must hold a Home Office Category 2 Precursor Chemical Registration.
2. A single declaration for a 12 month period may be accepted providing the University has purchased the substance at least three times in the previous 12 months.
3. Schools should record the acquisition of Category 2 substances.
4. Category 2 substances should, so far as is reasonably practicable, be kept securely.
5. Departments must inform the Safety Office if they wish to supply Category 2 substances to parties outside the University. This could constitute "trade" and additional parts of the Regulations (including the need to obtain a Home Office licence) might apply.

### **Category 3 substances**

Category 3 substances include the following:

- Hydrochloric acid;
- Sulphuric acid;
- Toluene;
- Ethyl ether;
- Acetone; and  
Methylethylketone.

1. The Regulations relating to Category 3 substances are not likely to be relevant to the University as they concern the export of substances to countries outside the EU.
2. There are no restrictions on the keeping & use of Category 3 substances other than normal health & safety considerations.

### **Category 4 precursors - medicinal products containing ephedrine/pseudoephedrine: new export control (outside of EU)**

This might have relevance for use of this material in fieldwork or collaborative work outside the EU.

This category is for the purposes of export control only, and has been introduced with effect from 30 December 2013. This will specifically affect medicinal products (both for human or veterinary use) containing either pseudoephedrine or ephedrine; wider control of these substances as category 1 Precursor Chemicals, when in non-medicinal product format, is unchanged.

A Home Office export licence is required where it is intended to ship these products outside of the EU. Exports will be subject to the Pre-Export Notification (PEN) process, whereby the importing country must 'validate' the proposed shipment.

The total length of time taken for an export application can be up to 27 working days, 15 days of which includes a PEN clearance period. This must be factored into the application timings, and applications made via the Home Office electronic portal, the National controlled Drug System (NDS). Before first application it might be necessary to provide the Home Office with a list of your relevant preparations to be uploaded on to NDS.

Exports within the EU are not subject to Home Office licence and are unaffected by these changes.

## List of Scheduled Substances and Codes

Full details available via the Home Office website – [Precursor Chart](#).

<b>Category 1</b>			
<b>Substance</b>	<b>CN designation (if different)</b>	<b>CN Code</b>	<b>CAS Number</b>
1-phenyl-2-propanone	Phenylacetone	2914 31 00	103-79-7
N-acetylanthranilic acid	2-acetamidobenzoic acid	2924 23 00	89-52-1
Isosafrol (cis + trans)		2932 91 00	120-58-1
3,4-methylenedioxyphenyl-propan-2-one	1-(1,3-Benzodioxol-5-yl)-propan-2-one	2932 92 00	4676-39-5
Piperonal		2932 93 00	120-57-0
Safrole		2932 94 00	94-59-7
Ephedrine		2939 41 00	299-42-3
Pseudoephedrine		2939 42 00	90-82-4
Norephedrine		ex2939 49 00	14838-15-4
Ergometrine		2939 61 00	60-79-7
Ergotamine		2939 62 00	113-15-5
Lysergic acid		2939 63 00	82-58-6
Alpha Phenylacetoacetonitrile (APAAN)		2926 90 95	4468-48-8
<b>Category 2</b>			
<b>Category 2A</b>			
Acetic anhydride		2915 24 00	108-24-7
<b>Category 2B</b>			

Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7
<b>Category 3</b>			
Hydrochloric acid	Hydrogen chloride	2806 10 00	7647-01-0
Sulphuric acid		2807 00 10	7664-93-9
Toluene		2902 30 00	108-88-3
Ethyl ether	Diethyl ether	2909 11 00	60-29-7
Acetone		2914 11 00	67-64-1
Methylethylketone	Butanone	2914 12 00	78-93-3

**Note:**

1. For Category 1 substances the list includes:
  - The stereoisomeric forms of the substances listed in this category not being cathine (also named (+)-norpseudoephedrine; CN code 2939 43 00; CAS No 492-39-7), whenever the existence of such forms is possible.
  - The salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of cathine.
2. For Category 2 substances the list includes the salts of the substances listed in this category, whenever the existence of such salts is possible.
3. For Category 3 substances the list includes the salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of hydrochloric acid and sulphuric acid.