Application for Licence for Category 1 Scheduled Substances (Precursor Chemicals)

*Applications are made in accordance with:*

* *Regulation (EC) No. 273/2004 (as amended) laying down the rules governing the monitoring of intra-Community trade.*
* *Regulation (EC) No. 111/2005 (as amended) laying down rules for the monitoring of trade between the Community and third countries in drug precursors.*

*The rules for the implementation of the above legislation are contained in:*

* *Commission Delegated* [*Regulation (EU) No 2015/1011*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_162_R_0003&from=EN) *repealing Commission Regulation (EC) No 1277/2005,*
* *Commission Implementing* [*Regulation (EU) No 2015/1013*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_162_R_0005&from=EN)*, and*
* *Commission Delegated* [*Regulation (EU) No 2016/1443*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1443&from=EN) *amending Regulations (EC) No 273/2004 and 111/2005.*

|  |
| --- |
| **SECTION 1: APPLICANT DETAILS** |
| **1.1 Applicant contact details** |
| Name: |       |
| Address: |       |
| Company registered address (if different): |       |
| Company registration number: |       |
| Telephone: |       |
| Fax: |       |
| Email: |       |

|  |
| --- |
| **SECTION 2: RESPONSIBLE OFFICER**  |
| **2.1 Responsible Officer contact details** |
| Name: |       |
| Address: |       |
| Telephone: |       |
| Fax: |       |
| Email: |       |
| **2.2 Details of relevant professional qualifications and/or experience in dealing with the sale, supply and exportation of scheduled substances** |
|       |
| **2.3 Description of the position and tasks of the Responsible Officer**  |
|       |

|  |
| --- |
| **SECTION 3: PREMISES** |
| **3.1 Business premises address** |
|       |
| **3.2 Have you previously held a licence for category 1 scheduled substances at the premises listed in 3.1?** |
| No [ ]  Yes [ ] If yes, please list the licence number of the last licence held and its expiry date:Licence number:      Expiry date:       |
| **3.3 Is the business premises in 3.1 listed on any other licence, registration or authorisation issued by the HPRA?** |
| (*e.g. medicinal product manufacturers or wholesale authorisation, controlled drugs licence or registration, scheduled substance registration, active substance registration or medicinal product broker registration)*No [ ]  Yes [ ] If yes, please list all licence, registration and authorisation numbers:       |
| **3.4 Description of all places the activities of production, manufacture, processing, placing on the market, possession, import, export and/or intermediary activities involving scheduled substances** *(attach separate document if necessary)* |
|       |
| **3.5 Measures taken to prevent the unauthorised removal of scheduled substances from the places listed in point 3.4** *(attach separate document if necessary)* |
|       |

|  |
| --- |
| **SECTION 4: ACTIVITIES** |
| **4.1 Purpose for which the licence is required** |
| *(State briefly, e.g.* *storage, manufacture, production, processing, trade, distribution, brokering, possession, import, export, placing on the market and/or intermediary activities. Sufficient information should be supplied to justify obtaining a licence.)*      |
| **4.2 Control of supplies** |
| Details of the precautions to be taken to prevent supply of scheduled substance(s) to unauthorised persons:       |
| **4.3 Scale of usage** |
| Anticipated annual scale of usage of the scheduled substance(s):       |
| **4.4 Preparations produced** |
| List any preparations or other products to be produced under the authority of the registration for which application is made:       |

|  |
| --- |
| **SECTION 5: LICENCE REQUIRED** *(Indicate with a tick the scheduled substances and primary activities for which licence is required.)*  |
| ***Scheduled Substance****(including their salts and stereoisomeric forms wherever such exist (not being cathine))*  | ***CN Code as stated in Annex I to Regulation (EC) No 273/2004 (as amended) and 111/2005 (as amended)*** | **Type of Licence** |
| ***To place on the market\*******(a)*** | ***To possess*** ***(b)*** | ***Import from outside the EU******(c)*** | ***Export outside of EU******(d)*** | ***Intermediary activities******(e)*** |
| 1-Phenyl-2-propanone (BMK) | 2914 31 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Diethyl (phenylacetyl) propanedioate(DEPAPD) | 2918 30 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Alpha-phenylacetoacetonitrile (APAAN) | 2926 40 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Chloroephedrine | 2939 79 90 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Chloropseudoephedrine | 2939 79 90 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| N-Acetylanthranilic acid | 2924 23 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Isosafrol (cis+trans) | 2932 91 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 3,4-methylenedioxyphenylpropan-2-one (PMK) | 2932 92 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Methyl 3-(1,3-benzodioxol-5-yl)-2- methyloxirane-2-carboxylate (PMK methyl glycidate) | 2932 99 00  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid (PMK glycidic acid) | 2932 99 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Piperonal | 2932 93 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Safrole | 2932 94 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMKethyl glycidate) | 2932 99 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| N-phenyl-1-(2-phenylethyl)piperidin4-amine (ANPP) | 2933 36 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 1-(2-phenylethyl)piperidin-4-one (NPP) | 2933 37 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| N-phenylpiperidin-4-amine (4-AP) | 2933 39 99 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Tert-butyl 4-anilinopiperidine1-carboxylate (1-boc-4-AP) | 2933 39 99 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl) | 2933 39 99 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Ephedrine | 2939 41 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Pseudoephedrine | 2939 42 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Norephedrine | 2939 44 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Ergometrine | 2939 61 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Ergotamine | 2939 62 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Lysergic Acid | 2939 63 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Alpha-phenylacetoacetamide (APAA) | 2924 29 70 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Methyl alpha-phenylacetoacetate (MAPA) | 2918 30 00 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)  | 2918 99 90  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 2‐methyl-3-phenyloxirane-2- carboxylic acid (BMK glycidic acid) | 2918 99 90 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 1. **Placing on the market** means any supply, whether in return for payment or free of charge of scheduled substances in the Union; or the, storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union.
2. **To possess** means the possession of a scheduled substance by a user who is engaged in the processing, formulation, consumption, storage, keeping treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances. A ‘user’ defines persons possessing scheduled substances for purposes other than placing them on the market.
3. **Import** means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92.
4. **Export** means any departure of scheduled substances from the customs territory of the Community, including the departure of scheduled substances that requires a customs declaration and the departure of scheduled substances after their storage in a free zone of control type I or free warehouse within the meaning of Council Regulation (EEC) No 2913/92.
5. **Intermediary activities** means any activity to arrange purchase and sale or supply of these precursor chemicals carried out to obtain agreement between two parties or to do so through acting on behalf of at least one of these parties without taking these substances into its possession or taking control of the carrying out of such transaction. This definition shall also include any activity involving purchase and sale or supply without the precursor chemicals being introduced into the customs territory of the Union.
 |
| **In the case of a mixture or natural product:**Tick if not applicable[ ] Name of the mixture or natural product:      Name and CN Code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 (as amended) and Annex to Regulation (EC) No 111/2005 (as amended) in the mixture or natural product:      Maximum percentage of such scheduled substances in the mixture or natural product:       |
| **Type of operations in the case of mixture or natural product** Description of the envisaged type of operations referred to in Regulation (EC) No 273/2004 as amended and Regulation (EC) no 111/2005 as amended:      [ ]  Possession[ ]  Placing on the market[ ]  Importing *(from outside the EU)*[ ]  Exporting *(to countries outside the EU)*[ ]  Intermediary activities Please give any additional details, particularly regarding intermediary activities:       |

|  |
| --- |
| **SECTION 6: CERTIFICATES AND FEES***(tick to confirm attachment of the below documents)* |
| **6.1** | Authenticated copy of the company’s Certificate of Incorporation | [ ]  |
| **6.2** | Certificate of good conduct of the applicant and Responsible OfficerORDocument showing that they offer the necessary guarantee for the proper conduct of operations | [ ] [ ]  |
| **6.3** | Proof of payment made to the Health Products Regulatory Authority. Please note purchase orders and cheques are not acceptable. Please contact controlleddrugs@hpra.ie for queries regarding fees. | [ ]  |

|  |  |  |
| --- | --- | --- |
| SECTION 7: declarationIn the event of the licence being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the licence and declare that the above particulars are, to the best of my knowledge and belief, correct.

|  |  |
| --- | --- |
| Signature:       | Date:        |

 *(Applications must bear the signature of the Responsible Officer)*  |

**Note:**

This application should be sent to:

Controlled Drugs Section

Compliance Department

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: controlleddrugs@hpra.ie