Application for Registration of Category 3 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.*

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| **SECTION 1: APPLICANT DETAILS** | | |
| **1.1** | | **Applicant company contact details**  Company name:  Address:  Company registered address (if different):  Company registration number:  Telephone:  Fax:  Email: |
| **SECTION 2: CONTACT PERSON** | | |
| **2.1** | **Contact details of manager or person responsible for precursor chemicals (Contact Person)**  Name:  Telephone number: | |
| **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 Contact Person** | |

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| **SECTION 3: PREMISES** | |
| **3.1** | **Business premises address** |

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| **SECTION 4: ACTIVITIES** | |
| **4.1** | **Purpose for which registration is required**  *(State briefly, e.g.* *import, export, placing on the market and/or intermediary activities. Sufficient information should be supplied in order to justify obtaining a registration.)* |
| **4.2** | **Scale of import, export, transit or intermediary activities**  Indication of the anticipated scale of import, export or transit of the scheduled substance(s): |
| **4.3** | **Control of supplies (including exportation)**  Details of the precautions to be taken to prevent diversion or supply of scheduled substance(s) to unauthorised persons: |
| **4.4** | **Preparations produced**  List any preparations or other products to be produced under the authority of the registration for which application is made: |

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| **SECTION 5: TYPE OF REGISTRATION REQUIRED**  *(Indicate with a tick the scheduled substances and primary activity for which registration is required.)* | | |
| **Details of Registration** | | |
| ***Scheduled Substance***  *(including their salts whenever such exist, not being the salts of hydrochloride acid and sulphuric acid)* | ***CN Code as stated in Annex I to Regulation (EC) No 273/2004*** | ***Export*** |
| Acetone | 2914 11 00 |  |
| Ethyl ether | 2909 11 00 |  |
| Methylethyl ketone | 2914 12 00 |  |
| Toluene | 2902 30 00 |  |
| Sulphuric acid | 2807 00 10 |  |
| Hydrochloric acid | 2806 10 00 |  |

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| Operators are exempt from registration where the sum of quantities concerned by their exports during the course of the preceding calendar year (1 January – 31 December) does not exceed the amounts indicated below. This exemption also applies to mixtures containing the substances below.   |  |  | | --- | --- | | **Substance** | **Annual threshold** | | Acetone | 50 kg | | Ethyl ether | 20 kg | | Methylethyl ketone (Mek) | 50 kg | | Toluene | 50 kg | | Sulphuric acid | 100 kg | | Hydrochloric acid | 100 kg | | Note: This includes the salts of these substances whenever the existence of such salts is possible. | |   In order to comply with registration requirements, if the above quantities are exceeded with the current calendar year, the operator must contact the Health Products Regulatory Authority immediately.  **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. |
| **Exports in the preceding year**  Details in summary form of the export transactions in the Category 3 scheduled substances concerned with the application, which have been made in the twelve months preceding the application, specifying in each case the total number of transactions and the amounts exported to each country:  *(Provide details on a separate page if necessary.)* |

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| SECTION 6: CERTIFICATES AND FEES | | |
| **6.1** | Authenticated copy of the company’s Certificate of Incorporation  *(tick to confirm attachment)* |  |
| **6.2** | Certificate of good conduct of the applicant and contact person  OR  Document showing that they offer the necessary guarantee for the proper conduct of operations  *(tick to confirm attachment)* |  |
| **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](mailto:controlleddrugs@hpra.ie) for queries regarding fees.  *(tick to confirm attachment)* |  |

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| SECTION 7: declaration  I hereby declare that, to the best of my knowledge and belief, that all the particulars given in this application are correctly stated.   |  |  | | --- | --- | | Signature: | Date: |   *(Applications must bear the signature of the Contact Person)*  Where the application is on behalf of a limited company, the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner. |

**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](mailto:compliance@hpra.ie)