DG Inspection/Authorisations Division/Specially Regulated Substances Entity/RD 12.04.1974 Team

Send BY POST to:
Federal Agency for Medicines and Health Products
DG Inspection – Authorisations Division – Substances RD 12.04.1974 Team
Avenue Galilée 5/03
1210 BRUSSELS

Or

Send BY EMAIL to: substances_HAA@fagg-afmps.be
Only when provided with the correct qualified electronic signatures (NO SCANS).

APPLICATION FOR A LICENCE FOR SUBSTANCES R.D. 12.04.1974

PRIVATE PERSON

According to art. 1 of the royal decree dated 12 April 1974 regarding some operations in connection with substances with hormonal, anti-hormonal, anabolic, beta-adrenergic, anti-infectious, anti-parasitic or anti-inflammatory effects, last revised by the R.D. dated 4 February 2002 (B.S. dated 28 February 2002).

☐ RENEWAL OF LICENCE NUMBER: indicate as appropriate**: NL/FR**

☐ NEW LICENCE REQUEST

1. IDENTIFICATIE VAN DE AANVRAGER

First name:	
Surname	
Address:	
E-mail:	
Tel./mobile:	
Signature:	

2. ACTIVITY SITE

The different addresses where the substances will be stored or used.
At least 1 mandatory. If this space is not sufficient, please add an attachment.

Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	

3. Activities (indicate the appropriate responses)
Note: import and export are regarded as in relation to the Belgian territory.

☑	Be in possession of	☑	Acquiring by payment or at no cost
☐	Import	☐	Export
☐	Transport	☐	Manufacturing of raw materials (not of medicine)
☐	Offering for sale	☐	Sale

4. SUBSTANCES and JUSTIFICATION

Please indicate on the next page the substances for which you are applying for a licence and provide below a brief description of the reasons for applying for this licence. **This will avoid additional questions from our service and potential delays in processing your licence application.** If this space is not sufficient, please add an attachment.

REASONS for applying for this licence:

SUBSTANCES:
Substances and their corresponding CAS-number for which the licence is requested (art. 1, §1 and §3 of the RD of April 12th 1974, amended last by the R.D. dated 4 February 2002).
In case of insufficient space, you may add an appendix to the application, to list the relevant substances and their corresponding CAS-number.

SUBSTANCE	CAS- number (Chemical Abstracts Registry Number)

Practical information

- Return the fully completed and signed application form:
  - **By POST, only if the original form has been signed (no copies or scans), to:**

    Federal Agency for Medicines and Health Products
    DG Inspection – Authorisations Division - Substances RD 12.04.1974 Team
    Avenue Galilée 5/03
    1210 BRUSSELS

  Or

  - **By E-MAIL, ONLY if the form has been provided with ALL the necessary qualified electronic signatures AFTER it has been completed in full, to:**
    substances_HAA@fagg.be
    (signature via ID card or see https://economie.fgov.be/fr/themes/line/commerce-electronique/signature-electronique-et).
    Company tokens are usually not qualified electronic signatures and may be considered inadmissible.
    The signature can be added by double-clicking on the signature field. Once signatures have been added, it is no longer permitted to edit the form, so please complete the form in full before adding the signatures. If the form does need to be changed again, the signatures must be re-applied. Otherwise, the application will be inadmissible.

- **The fee amount** is indexed annually and can be viewed at any time on the FAMHP website.
- **Every modification** (responsible persons, address, substances…) needs to be communicated to us (by post or e-mail) **within 15 days** by a responsible person mentioned on the licence. The form to be used for this is available on the FAMHP website.