



香港特別行政區政府漁農自然護理署

AGRICULTURE, FISHERIES AND CONSERVATION DEPARTMENT
THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION

(如需中文版本可向本署索取)
(Chinese version is available on request)

A Guide to Application for Pesticide Registration

Pesticide Registration

The Pesticides Ordinance (Cap. 133) was introduced to regulate the import, manufacture, repackaging, storage, labelling and sale of all pesticides. Under the Pesticides Ordinance, only registered pesticides may be imported into and distributed for use in Hong Kong.

The term “pesticide” covers all chemical and biological pesticides in whatever forms and for whatever uses. For instance, it includes agricultural pesticides, plant growth regulators, antifouling paints for ship bottom, moth proofers, insecticide aerosol, ant/fly/roach dust, poison bait, mosquito coil/mat, rat poisons, insecticide paint, insecticide impregnated cabinet paper and aquarium use algicide. However, mechanical pest control devices and pharmaceutical preparations containing pesticide ingredients such as insecticidal shampoo/cream used for treatment of disease in human are excluded from the control of this Ordinance.

Any person may apply for registration of a pesticide according to the method laid out below, but only licensed persons may import, sell or supply registered pesticides and only holders of permits may import unregistered pesticides. For details on the application for pesticide licences and permits, please refer to relevant guidelines.

Application Method

Application for registration of pesticides can be made to the Plant and Pesticides Regulatory Division, Agriculture, Fisheries and Conservation Department at 5/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon. Postal application should be addressed to the Director of Agriculture, Fisheries and Conservation and stated with "Application for Pesticide Registration".

Application forms and guidelines can be obtained from the above-mentioned office or downloaded from AFCD's website at <http://www.afcd.gov.hk>.

Application Fee

A fee of HK\$2,880 is charged for an application for registration of a pesticide. The fee is not refundable no matter whether the application is approved or not. The fee can be settled by one of the following methods -

- (i) In person: Cash, Crossed cheque (made payable to “The Government of the HKSAR”) or EPS;
- (ii) By post: Crossed cheque (made payable to “The Government of the HKSAR”);
or
- (iii) Online payment: Credit card (an email address should be provided on the application form to receive a payment URL).

Documents Required in Application for Registration

Please send to this Department the completed application form with the following documents:

1. Authorization letter (applicable to overseas applicant who authorized local agent to handle their application for registration)
2. The technical information required for pesticides registration are listed in “Appendix A - Information Requirement for Pesticide Registration” which include:
 - Chemical and physical properties of the active ingredient(s) and the formulated product
 - Material Safety Data Sheet of the active ingredient(s) and the formulated product
 - Information on toxicity of the active ingredient(s) and the formulated product
 - Information on environmental studies of the active ingredient(s) and the formulated product
 - Complete composition and functions of all components in the formulated product
 - Detailed method of analysis of the formulated product
 - Efficacy test of the formulated product
 - Measures to be taken in case of intoxication
 - Registration status in other countries
3. Where the pesticide is intended for use on food crops, the applicant shall provide the Maximum Residue Limit(s) of the pesticide as stipulated in Schedule 1 to the Pesticide Residues in Food Regulation (Cap. 132CM) unless such pesticide is an exempted pesticide stipulated in Schedule 2 to the said Regulation.
4. Original labels and labels to be used on the formulated products for local supply and retail sale submitted by manufacturer. Applicants may also request this Department to give suggestion on label content pursuant to regulation 12 of the Pesticides Regulations (Cap. 133A).

All the technical data documents should be submitted in full report format. The reports should contain details on experimental methods and results issued by the corresponding organization. In general, experiments conducted by research/examination institutes in China and other countries according to the OECD Guidelines or the “Toxicological test methods of pesticides for registration” of China, the reports are acceptable to this Department as supporting documents for a pesticide registration application.

If the original technical report and information is written in languages other than Chinese and English, the applicant should submit a certified translated copy in Chinese or English.

General Information

1. All pesticides will be classified into two parts (Part I and Part II) according to their usage, formulation and toxicity. General domestic pesticides ready for immediate use are classified as Part I and other pesticides such as agricultural pesticides and pest control chemicals are classified as Part II pesticides.

2. If the combination of active ingredients, formulation and/or concentration (exceeding the limitation) of a pesticide is different from those already listed in the Register of Pesticides (the Register), the applicant should submit a new application for registration.
3. When the registration of a pesticide is approved, the applicant will be notified and details of the pesticide will be entered into the Register. The Register is available for public inspection and the following information relating to each registered pesticide is entered into the Register:
 - (a) the chemical name and the common name, if any, by which the pesticide is known and under which it is to be sold or supplied;
 - (b) the concentration of the active ingredient(s) and formulation of the pesticide permitted for retail sale or supply;
 - (c) the name and address⁽¹⁾ of each person who applied for the registration of the pesticide; and
 - (d) the conditions, if any, subject to which the pesticide is registered.
4. If the Director of Agriculture, Fisheries and Conservation refuse the registration of a pesticide, a "Notice of Refusal of Registration" will be issued and state the reason for refusal.

Important Notes

In compliance with and subject to the provisions in Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights under the World Trade Organization, all data relating to undisclosed tests or other data, the origination of which involves a considerable effort, upon being submitted to the Agriculture, Fisheries and Conservation Department for the purpose of applying for the registration of a pesticide, are:

- considered and kept confidential;
- only viewed by a limited number of Government officers on a need-to-know basis for registration; and
- never used in other registration applications unless under written authorization from the supplier of the original data.

Enquiry

If there is any enquiry regarding application for pesticide registration, please contact the Plant and Pesticides Regulatory Division of this Department.

Phone No.: (852) 2150 7010

Fax No.: (852) 2314 2622

Email Address: pestreg@afcd.gov.hk

Website: <http://www.afcd.gov.hk>

⁽¹⁾ Applicants may provide business address or correspondence address.



香港特別行政區政府漁農自然護理署

AGRICULTURE, FISHERIES AND CONSERVATION DEPARTMENT
THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION

附件 A—除害劑註冊所需資料

Appendix A — Information Requirement for Pesticide Registration

注意事項 NOTES:

- 所有技術資料文件須以完整報告的形式提交。技術報告須備有所屬機構簽發的詳細實驗方法及結果。
All the technical data documents should be submitted in full report format. The reports should contain details on experimental methods and results issued by the corresponding organization.
- 如提交的技術報告及資料的原文為中文或英文以外的語文，申請人必須提交一份核證為該文件的中文或英文譯本。
If the original technical report and information is written in languages other than Chinese and English, the applicant should submit a certified translated copy in Chinese or English.

A. 活性成分的資料

INFORMATION ON THE ACTIVE INGREDIENT(S)

1. 通用名稱 Common name(s) (ISO 或 or ANSI 或 or BSI)
2. 化學名稱 Chemical name(s) (IUPAC)
3. 除害劑類型 Pesticide group
4. 其他名稱(商標／產品名稱) Other name (Trade/Brand name)
5. 分子式和結構式 Empirical and structural formula
6. 分子量 Molecular weight
7. 活性成分的物料安全資料表 MSDS of the active ingredient(s)
8. 物理特性 Physical properties:
 - a. 溶點 melting point
 - b. 沸點 boiling point
 - c. 比重 specific gravity
 - d. 折射率 refractive index
 - e. 蒸氣壓力 vapor pressure (mmHg 於 at 20°C)
 - f. 其他有關揮發性的資料 other volatility data
 - g. 活性成分在水中的可溶性
solubility of the active ingredient(s) in water
 - h. 活性成分在水中的穩定性
stability of the active ingredient(s) in water
 - i. 活性成分在其他溶劑的可溶性
solubility of the active ingredient(s) in other solvents
 - j. 在水與不混溶的有機溶劑之間的分配系數
partition coefficient between water and an immiscible organic solvent
 - k. 其他詳情 others

9. 化學特性 Chemical properties:

- a. 穩定性(在空氣、水中、光穩定性、熱力降解)
stability (in air, in water, photostability, thermal degradation)
- b. 在配方中使用的有機溶劑下的穩定性
stability in organic solvents used in the formulation
- c. 在水中的半衰期 half-life in aquatic system
- d. 在土壤中的半衰期 half-life in soil
- e. 分解物 breakdown product
- f. 腐蝕性 corrosiveness
- g. 閃點 flash point
- h. 可燃性 flammability
- i. 其他詳情 others

10. 詳細產品製造方法(高純度的活性成分／原藥)

Details of the method of manufacturing (pure active ingredient(s)/technical material(s))

11. 詳細分析方法(高純度的活性成分／原藥)

Details of the method of analysis (pure active ingredient(s)/technical material(s))

12. 在製造過程中，與活性成分有關的已知污染物或雜質

Known contaminant(s) or impurity(ies) associated with the active ingredient(s) in the manufacturing process

B. 配方製品資料

INFORMATION ON THE FORMULATED PRODUCT

1. 包裝類別

Type of packing

2. 完整組合成分及作用(包括非主成分的化學屬性)

Complete composition and functions (including chemical identity of inert ingredients)

3. 配方製品的物理狀況及性質

Physical condition and nature of the formulated product

4. 配方製品的物料安全資料表

MSDS of the formulated product

5. 配方製品的穩定性及其有效期

Stability of the formulated product and its shelf life

6. 對包裝物料和施用器械的腐蝕性

Corrosiveness towards packing materials and application equipment

7. 在貯存及施用情況下的可燃性

Flammability under storage and application conditions

8. 配方製品的詳細製造方法

Details of the method of manufacturing the formulated product

9. 配方製品的詳細分析方法

Details of the method of analysis of the formulated product

10. 配方製品的效能測試

Efficacy test of the formulated product

11. 植物及食物中殘留物的詳細分析方法

Details of method of analysis of residues in plant and foodstuff

12. 不能與其他除害劑混和的資料(如該配方製品擬供作農業用途)

Incompatibility with other pesticide(s) (for the formulated product intended for agricultural use only)

13. 關於施用、存放、運輸或火警時的建議處理方法和注意事項
Recommended methods and precautions concerning handling, storage, transport or fire, etc.
14. 淨化／中和劑
Decontamination/neutralizing agent
15. 配方製品及其容器的棄置方法
Disposal method for the formulated product and its container

C. 有關除害劑使用的資料

INFORMATION ON PESTICIDE USAGE

1. 在註冊國家已獲批准的產品標籤，小冊子(例如註冊證書、註冊編號、註冊限制、註冊條件)
Approved label, product brochure in registered countries (e.g. registration certificates, registration no., registration restrictions, registration conditions)
2. 建議用途(例如使用方式，施用地點)
Recommended uses (e.g. use pattern, application sites)
3. 使用說明(例如施用方法和劑量)
Instruction for use (e.g. application method and dosage)
4. 不可使用該除害劑的特殊情況
Special conditions under which the pesticide may not be used
5. 標籤上注意事項
Precautionary statements on label
6. 目標生物
Target organism(s)
7. 對有害物的影響(例如接觸、吸入中毒、消化中毒、內吸性、真菌毒性)
Effects on pests (e.g. contact, inhalation poison, stomach poison, systemic, fungitoxic)
8. 作用模式
Mode of action
9. 植物藥害(只限應用於植物上的除害劑)
Phytotoxicity (for pesticide applying on living plants only)
10. 跟其他除害劑的相容性
Compatibility with other pesticides
11. 應用於密閉環境的除害劑：可再進入的相隔時間
For pesticide applied to closed environment: Re-entry lapse time
12. 擬使用於本地糧食作物的除害劑
For pesticide intended for use on local food crops:
 - a. 採收安全間隔期
pre-harvest interval
 - b. 在已予註冊國家，同一除害劑的最高殘餘限量及每日允許攝入量 及
Maximum Residue Limit(s) and acceptable daily intake (ADI) in countries where the same pesticide has been registered and
 - c. 載於《食物內除害劑殘餘規例》(第 132CM 章) 附表 1 的同一除害劑的最高殘餘限量項目編號，或如同—除害劑載於《食物內除害劑殘餘規例》(第 132CM 章) 附表 2，其於附表 2 的項目編號(視乎何者適用)
item number(s) of the Maximum Residue Limit(s) of the same pesticide which is/are available in Schedule 1 to the Pesticide Residues in Food Regulation (Cap.132CM), or the item number of the same pesticide if it is included in Schedule 2 to the Pesticide Residues in Food Regulation (Cap.132CM) (as appropriate)

D. 活性成分與配方製品的毒性資料

INFORMATION ON TOXICITY OF THE ACTIVE INGREDIENT(S) AND THE FORMULATED PRODUCT

1. 活性成分及配方製品對哺乳類動物的急性毒性
Acute toxicity of the active ingredient(s) and the formulated product in mammals:
 - a. 急性口服致死中量
acute oral toxicity (LD50)
 - b. 急性經皮致死中量
acute dermal toxicity (LD50)
 - c. 吸入致死中量
inhalation toxicity (LC50)
 - d. 對眼睛的刺激程度
degree of irritation to eyes
 - e. 對皮膚的刺激／敏感程度
degree of skin irritation/sensitization
2. 活性成分與配方製品的慢性毒性
Chronic toxicity of the active ingredient(s) and the formulated product
3. 活性成分與配方製品的無察覺有害作用劑量
No observable effect level of the active ingredient(s) and the formulated product
4. 活性成分的其他毒性研究(長期／短期)
Supplementary toxicity studies (long/short term) of the active ingredient(s) on:
 - a. 致癌作用
carcinogenicity
 - b. 對生育的毒性，包括致畸作用
reproductive toxicity including teratogenicity
 - c. 致突變作用
mutagenicity
 - d. 對神經的毒性
neurotoxicity
5. 活性成分在哺乳類動物的存留程度和新陳代謝的分解途徑
Persistence and metabolic breakdown pathway of the active ingredient(s) in mammal

E. 活性成分與配方製品的環境學研究資料

INFORMATION ON ENVIRONMENTAL STUDIES OF THE ACTIVE INGREDIENT(S) AND THE FORMULATED PRODUCT

1. 在土壤中的積聚及殘效影響
Accumulation and residual effect in soil
2. 在魚類／其他水中生物的積聚
Accumulation in fish/other aquatic organisms
3. 生物積聚特性
Bioaccumulation property
4. 土壤新陳代謝，有氧及無氧新陳代謝和分解物
Soil metabolism, aerobic and anaerobic metabolites and breakdown product
5. 在水中的生物退減作用，有氧及無氧新陳代謝和分解物
Biodegradation in aquatic systems, aerobic and anaerobic metabolites and breakdown product
6. 土壤的吸收和非吸收作用與及新陳代謝和分解物的流動量
Adsorption and desorption in soil and mobility of metabolites and breakdown product

7. 水中的附吸及解吸作用
Adsorption and desorption in water
8. 活性成分及配方製品對益蟲的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to beneficial insects
9. 活性成分及配方製品對捕食性昆蟲／寄生性昆蟲的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to predatory/parasitic insects
10. 活性成分及配方製品對魚類的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to fish
11. 活性成分及配方製品對鳥類的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to birds
12. 活性成分及配方製品對禽畜及寵物的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to livestock and pets
13. 活性成分及配方製品對野生生物的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to wildlife
14. 活性成分及配方製品對水中無脊椎動物的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to aquatic invertebrates
15. 活性成分及配方製品對土壤微生物的毒性或影響
Effect or toxicity of the active ingredient(s) and the formulated product to soil microorganisms
16. 活性成分及配方製品對土壤生態的影響
Impact of the active ingredient(s) and the formulated product on soil ecology
17. 在泥土中或建築材料上的殘效影響(尤其是除草劑／能與泥土混和的內吸性除害劑，熏蒸劑)
Residual effect in soil (especially for herbicides/systemic soil-incorporation pesticides, fumigants) or building materials
18. 活性成分在環境中的存留程度和新陳代謝的分解途徑
Persistence and metabolic breakdown pathway of the active ingredient(s) in the environment
19. 活性成分及配方製品對非目標有害物的毒性
Toxicity of the active ingredient(s) and the formulated product to non-target pests

F. 中毒時須採取的措施

MEASURES TO BE TAKEN IN CASE OF INTOXICATION

1. 發生活性成分／配方製品中毒事件時所應進行的急救治療
First aid treatment for the active ingredient(s)/formulated product intoxication incidents
2. 活性成分／配方製品的解毒劑
Antidote(s) for the active ingredient(s)/formulated product

G. 在其他國家的註冊情況

REGISTRATION STATUS IN OTHER COUNTRIES

倘有關除害劑曾在其他國家註冊，請註明其配方，活性成分濃度，使用方式及所受管制(如有的話)。註冊文件包括已在該國審批的標籤及小冊子亦應一併遞交。

Please specify the formulation, concentration of the active ingredient(s), use pattern, and restrictions (if any) placed on pesticide if registered in other countries. Registration documents including approved original label and brochure in registered countries should also be supplied.