



**INSPECTORATE OF PUBLIC HEALTH**  
**Department of Health Protection**

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**EXPLANATORY NOTES TO APPLICATION FORM**

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One of the stipulations of the Pesticides Law (Landsverordening, P.B. 1961, no 116) is that pesticides can only be marketed if the Inspector of Public Health has been notified at least three months in advance. Article 2 of this Law describes the procedure of the above-mentioned notification and stipulates that a sample of the pesticide has to be submitted.

This explanatory note has been designed to facilitate the notification/ application procedure for pesticides. The applicant is required to submit scientific studies e/o publications to support their claim that the product is suitable to be marketed.

When the submitted data is considered to be insufficient, the applicant will be requested to supply additional information. Incomplete applications will not be processed.

**ALL SUBMITTED DOCUMENTS ARE CONFIDENTIAL**

Foreign suppliers can send their data directly to the Inspectorate of Public Health, Department of Health Protection. The data provided will be regarded strictly confidential, even with respect to the local applicant.

## **THE SUBMISSION OF THE APPLICATION FORM**

- The application form can be obtained free of charge at the Inspectorate of Public Health, Department of Health Protection.
- Incomplete application forms will not be processed.
- An appendix must be submitted for answers to all questions marked with \*. Appendices must be numbered to correspond to the numbering of the particular questions on the form.
- The name or code of the product in the appendices must correspond to the names used on the application form.
- The application form should be completed in Dutch, English, or Spanish.
- Appendices may be submitted in Dutch, English or Spanish.
- Only typewritten or digitally completed application forms will be accepted.

## **EXPLANATION OF THE QUESTIONS**

The application form is subdivided into four different parts in order to comply with the subdivision of article 2 of the Pesticide Law (Landsverordening, P.B. 1961, no 116).

The subdivision of the application form is as follows:

- A. General information
- B. Data of the active ingredients
- C. Data of the composition of the formulated pesticide
- D. Data of instructions for use

All questions have to be completely answered. Further information can be obtained at the Department of Health Protection.

### **PART A:**

#### **GENERAL INFORMATION**

##### **A1: Name, address and telephone number of the applicant.**

The complete address of the applicant is necessary; a P.O. Box number alone is unacceptable.

##### **A2: Name and address of the manufacturing company of the pesticide.**

This question requires no further explanation.

**A3: Name of the product as it will appear on the packaging.**

If the definitive trade name is not yet known a code name may be used to begin the processing of the application as a temporary measure.

**A4: Chemical and/or common name (ISO-name) of the active ingredient(s).**

- Chemical name: According to the chemical nomenclature.
- Common name: According to the ‘International Organization for Standardization’ (ISO).

**A5: Brief description of intended use.**

Short description of:

- The nature of the product (insecticide, herbicide, fungicide)
- The areas of application for which the product is recommended (e.g., in cultivation of certain agricultural crops, in hospitals, animal shelters etc.).

**A6: Form in which the product is supplied and its net weight.**

- Form: The nature of the formulation, e.g. emulsion, aqueous solution, alcohol solution, liquid in spray can, shampoo, soluble powder, spray powder, fumigant, vaporizer, etc.
- Net weight: The package size to be marketed (volume, weight etc.).

**A7\*: Country(ies) in which the pesticide has already been approved, registered or authorized.**

This question has to be answered in case that the pesticide to be registered does not contain EPA#. When the product does contain an EPA#, it is sufficient to record this #.

In case that an EPA# is not available for the pesticide to be registered, then the countries in which the pesticide has already been approved must be recorded, and a copy of the certificate of competent authority of land of origin has to be attached as appendix to this application.

**PART B:**

**DATA OF THE ACTIVE INGREDIENTS**

A separate part B has to be filled in for every active ingredient.

**B1: Chemical name and common name of the active ingredient.**

See also A4. See MSDS of the active ingredient.

**B2: Manufacturer of the active ingredient.**

Mention the name of the manufacturer(s) of the active ingredient. In case the complete composition of the product contains more than one active ingredient and the ingredients are from different manufacturers, all manufacturers must be mentioned.

**B3\*: Physical and chemical properties of the active ingredient.**

Data such as color, odor, liquid, gas, powder, solubility of the particular ingredient in water, melting point, boiling point, density, corrosive, flammability. This information can most probably be obtained from the MSDS sheet of the particular ingredient.

Send MSDS of the active ingredient as an appendix

**B4: Empirical formula and molecular weight.**

This information can most probably be obtained from the MSDS sheet of the particular ingredient. Search for this information on the web in case that this information can not be found on the MSDS of the active ingredient.

**PART C:**

**DATA OF THE COMPOSITION OF THE FORMULATED PESTICIDE**

Composition of the final product; active ingredients and inert ingredients.

**C1\*: Complete composition:**

**Active ingredients and inert ingredients.**

Complete qualitative and quantitative composition is required. This means that every ingredient in the composition will be mentioned together with their corresponding amounts.

- The composition of liquids needs to be stated in grams per liter at 20 °C or in mass percentage (= mass of the specific ingredient divided by the complete mass of the composition, the answer times 100).
- The composition of spray cans needs to be mentioned in mass percentage.

An EPA# is essential in case that the inert ingredients can not be identified. EPA# has to be recorded. When no EPA# is available for the particular pesticide then it is necessary to identify all inert ingredients.

**C2\*: a. Analysis method to determine the presence of the active ingredient in the composition of the pesticide.**

- b. Laboratory result which guarantees the amount of active ingredient claimed on the label. This can be ignored if the pesticide contains an EPA#.**

**C3\*: Physical and chemical properties of the commercial product.**

Data such as color, odor, liquid, gas, powder, solubility of the final product in water, melting point, boiling point, density, corrosive, flammability.

This information can be most probably obtained from the MSDS sheet of the final product, send this MSDS as an appendix.

**C4\*: Stability and Shelf life at 25 °C.**

Indicate here the period during which the product remains adequately effective under normal conditions, the active substance does not significantly deteriorate, the physical and chemical properties continue to conform to reasonable requirements and there are no changes which might adversely affect the properties of the product.

If the shelf life is stated to be “unlimited” this must be supported by a test report (to be submitted as an appendix).

**C5: Are there products or substances with which the pesticide is incompatible?**

Indicate the products with which the active ingredients, inert ingredients, or final product might react/ interact in a way which can adversely affect the efficiency of the pesticide or might be hazardous.

**PART D:**

**DATA OF INSTRUCTION FOR USE**

An appendix needs to be attached for the complete answer to questions D1 and D2.

**D1\*: Draft instruction for use.**

The draft instruction for use should form the basis for the definitive instruction for use on the packaging. Leaflets or brochures, although always very appreciated as appendices to the applications, can not be accepted as draft instructions for use.

It must be clear from the text for what purposes the product can be used, where and in what manner it must be applied and what factors are important for an effective result.

The draft instructions for use must be clear and complete on the following points:

- The organisms to be repelled or controlled.
- The objects on or in which use is recommended. For example:
  - a. Agriculture, report all cultivation for which use of the particular product can be desired.
  - b. Animal sector, report animal species on which product can be used. Indications such as ‘livestock’, ‘domestic animals’, ‘birds’ etc., are not sufficient. It must be clear on what species of the livestock and domestic animals use is recommended; in the case of birds, it must be clear whether poultry, pigeons, etc. are meant.
  - c. Industrial use, mention for which areas the product is intended for use. The areas of application and the branch of industries should be specified as clearly as possible. For example floors, ceilings, equipment, food preparation surfaces, etc. in vegetable processing industry, bakeries, slaughterhouses, restaurant kitchens.
  - d. Domestic use, state whether use is recommended in living rooms, bedrooms, kitchens or store rooms.
- The dosage or concentration of use.
- It is recommended to mention the minimum and maximum dose coupled to a specific treatment.
- The application time (What moment/ time application is most effective)
- In case treatment must be repeated, indicate time intervals.
- The methods of application. Indicate here, for example, whether the treatment is by rows or areas, treatment of surfaces or complete rooms, immersion of objects, etc.
- Mention if special equipment is needed for application of the product. Technical information of the equipment needs to be reported in case an equipment is needed for application (droplet size,

spray pressure, etc.). Description of such non conventional equipment must be submitted as an appendix.

- Safety indications. Safety regulations, precautions, and warnings must be mentioned.

Photocopy of label must be submitted as an appendix.

In case non conventional equipment is needed, a description of equipment has to be submitted as appendix.

**D2: Circumstances which have influence on effectiveness of the product.**

Temperature influences, humidity etc.

**D3: Type and size of the package and method of closure.**

Mention the packaging material (glass, plastic, etc.) and whether adequate closure is guaranteed where applicable.

**D4: Are the containers (packaging) intended to be reused or refilled?**

This question requires no further explanation.

**D5: Instructions for disposing of spillage or old stock.**

Considering the chemical and physical properties of the product, an adequate disposal method for spillage and old stocks must be given, describing the disposal method.

**D6: Ways of disposal of the empty containers or packages.**

Indicate the most effective and responsible way to dispose of the empty containers with the least harm to the environment.