Environmental Protection Administration
Executive Yuan, R.O.C.
Application for the Permit of Environmental Agents

<table>
<tr><td rowspan="9">I. Application</td><td colspan="6">(1)New application：□Manufacturing Permit □Import Permit</td></tr>
<tr><td colspan="6">(2)Permit number：EPA No.（following item 2 and 3 are not required for applicant(s) who apply to extension, modification, replacement, renewal, cancellation, commission the manufacture or packaging）</td></tr>
<tr><td colspan="6">(3)Extend the expiration date of permit to (Y) (M) (D)</td></tr>
<tr><td colspan="6">(4)Other applications and instructions： □Reissue□Renewal□Cancellation</td></tr>
<tr><td colspan="6">□Modification：</td></tr>
<tr><td colspan="6">the content of original registration:</td></tr>
<tr><td colspan="6">□Commission the manufacture, Be commissioned factory:</td></tr>
<tr><td colspan="6">□Packaging content and packaging factory：</td></tr>
<tr><td colspan="6">□Component’s amount：</td></tr>
<tr><td rowspan="8">II. Environmental Agents</td><td>Category</td><td colspan="5">□Environmental sanitation agents
□Pollution-preventive agents
□Environmental microbial agents</td></tr>
<tr><td>Classification</td><td colspan="5">□General use □Restricted use □Technical grade</td></tr>
<tr><td>Bacterium Source</td><td colspan="5">Environmental microbial agents: □Domestic □Foreign
□Genetic Engineering</td></tr>
<tr><td>Chinese product name</td><td colspan="2"></td><td>Foreign product name</td><td colspan="2"></td></tr>
<tr><td>Formulation type</td><td colspan="2"></td><td>Packing</td><td colspan="2"></td></tr>
<tr><td>Performance</td><td colspan="5"></td></tr>
<tr><td>Components and contents</td><td colspan="5"></td></tr>
<tr><td rowspan="3">III. Manufacturer(s)</td><td>Name</td><td colspan="3"></td><td rowspan="3">Seal of Review</td><td rowspan="3"></td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td>Foreign manufacturer’s address</td><td colspan="3"></td></tr>
<tr><td rowspan="5">IV. Basic information</td><td>Company name</td><td colspan="3"></td><td rowspan="3">Application manufacturer’s seal</td><td rowspan="3"></td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td>Profit-seeking enterprise I.D. number</td><td colspan="3"></td></tr>
<tr><td>Responsible person(s)</td><td></td><td>Seal of responsible person(s)</td><td></td><td>Professional personnel</td><td></td><td>Seal of professional personnel</td><td></td></tr>
<tr><td rowspan="2">Contact person</td><td></td><td>TEL No.</td><td></td><td>Fax No.</td><td colspan="2"></td></tr>
<tr><td>E-mail</td><td colspan="5"></td></tr>
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Application Date： (Y) (M) (D) Manufacturer’s application number:

Certificate(s)

Manufacturing Permit	Import Permit
☐Photocopy of company license or company registration certificate (not applicable for non-company applicant) ☐Photocopy of business registration cause certificate ☐Photocopy of personal identification of the responsible person ☐Photocopy of factory registration (Note 1) ☐Photocopy of approval for the establishment of professional technician personnel ☐Photocopy of approval document for technical grade transferring of environmental agent or authorization document for sourcing the technical grade ☐Photocopy of approval letter of sample for registration as environmental agent (Note 4) ☐Original manufacturing permit of environmental agents	☐Photocopy of company license or company registration certificate (not applicable for non-company applicant) ☐Photocopy of business registration certificate ☐Photocopy of personal identification of the responsible person ☐Photocopy of environmental agents vendors permission license ☐Notarized original certificate of manufacturing and sales by the top authority of country of origin ☐Notarized authorization letter of distribution of the original overseas vender ☐Notarized original document of authorization letter of distribution, issued by the overseas vender within 2 years ☐Information which is sufficient to certify the validation of original permits of manufacture and commercialization certification (such as information from governmental website or other governmental documents) ☐Overseas product commercialized information (product label) ☐Photocopy of approval letter of sample for registration as environmental agent ☐Statement of product legal liability (essential for the amendment of product permit holders) ☐The final manufacturing date, lot number and quantity of environmental agent ☐Certificate for agreement of foreign original manufacturers ☐Certified document issued by the overseas manufacturer ☐Original import permit of environmental agents

Annotation: please attached these attached certificates (the original or copy) in the paper format of A4, and don't plaster.

Area to add the front of the photocopies for personal identification document of statutory responsible person(s)	Area to plaster the back of the photocopies for personal identification document of statutory responsible person(s)

The physical, chemical, and biological information for technical grade or Finished product

I. Chemical information

(I)Chemical name

(II)Chemical formula（must contain molecular formula and structural formula）

(III)Common name

(IV)character instruction

(V)Product's mechanism and efficiency

(VI)The basis or theory for formulation type and dosage (suggested formulation type and dosage of the original manufacturer provided by technical grade)

(VII)Component discriptions of technical grade (not required for manufacturers

applies to general use or restricted use for environmental agents, and manufacturers with the technical grade source of import permit application already registered domestically)

1.Original manufacturer's name

2.Address (includes company and factory)

3.Active ingredients and concentration

4.Other ingredients and concentration

5.List the ingredients and concentration of known impurity

(VIII)Instruction of finished product (technical grade only have to provide the information in following 1 and 2)

1.Package materials

2.Specifications (packing) (import permit should provide the packing instruction of original manufacturer)

3.Active ingredients and other ingredients concentration

II. Physical and chemical details

(I)The physical and chemical information attached in technical grade (not required for manufacturers apply to general use and restricted use environmental agents, and manufacturers with the technical grade source of import permit application already registered domestically)

1.Physical state

2.Color

3.Odor
4.pH
5.Melting point or Boiling point
6.Density, specific gravity
7.Vapor pressure
8.Solubility
9.Stability
10.Flammability
11.Miscibility
12.Explosibility
13.Storage Stability
14.Partition coefficient
15.Dissociation constant
16.Somerization rate of cis- and trans-

(2)Physical and chemical information attached in finished article

1.Physical state
2.Color
3.Odor
4.pH value
5.Density, specific gravity
6. Flammability
7. Miscibility
8. Explosibility
9.Storage stability

III. Biological information (only required for environmental microbial preparations)

(1)Scientific name
(2)The source of microbial strain
(3)Physical status
1.Color
2.Odor
3.pH
(4)Growth condition and limitation
(5)Pathogenicity

(6)Bacterium appearance

(7)Biochemical characters (required for environmental microbial agents, and includes: Gram stain, oxygen demand, utilization or decomposition of carbohydrate, utilization or decomposition of special substances, capacity for forming enzyme and toxin, and the factor, condition, and limitation of biosynthesis)

(8)Metabolite

(9)Genetic engineering bacterium (required for genetic engineering manufacturers)

1.Genetic engineering organisms' category: plant, animal, microorganism, and others

2.Recipient organisms: Chinese name, scientific name, taxonomy, and safe grade

3.Target gene: title, donor organisms, and biological function

4.Vector: title, source, marker gene, and report gene

5.Genetic algorithm: genetic operation type

6.Safe grade of genetic engineering organisms and conclusion

Remarks:

1. Physical state: indicates the description of appearance, such as solid, granular, or volatile liquid.
2. pH: equal to H_2SO_4 or NaOH, or pH value; the one which can be diluted or dispersed in water have to determine at 20℃ or 25℃.
3. Melting point or Boiling point: liquid state in ambient temperature needs information about boiling point (or boiling range), but solid state needs the information of melting point (or melting range).
4. Density, specific gravity, or apparent specific gravity: required for the one which is liquid state or solid state in ambient temperature, but not for spray.
5. Vapor pressure: required for a melting point less than or equal to 30℃, and should be determined at 25℃.
6. Solubility: indicates the solubility of distilled water and other representative polar and non-polar solvents under 20℃ or 25℃.
7. Stability: includes (1) the sensitivity against metal and light; and (2) the stability under ambient temperature and different temperature.
8. Flammability: required for products contain combustible liquid, and provide with flash point (closed or open).
9. Miscibility: required for the one which is emulsion and have to mix and dilute with petroleum distillates solvents.

10. Explosibility: required for product with potential explosive substances.
11. Partition coefficient: general indicates octanol / water partition, required for non-polar organic products.
12. Dissociation constant: based on requirement of actual case.
13. Special standards of finished articles are based on case requirement.
14. Import permit application should attach the physical and chemical information provided by original manufacturers.
15. Scientific name: scientific name, applications in environment sanitation includes genus, and species. The title or strain should be marked if there are subspecies, or mutation; application in pollution prevention should include genus and species of main bacteria.
16. The source of microbial strain: have to be marked as local or imported, native screening or genetic engineering.
17. Pathogenicity: host, symptom, and pathology.
18. Colony appearance: shape, color, contour of spore, and size.
19. Biochemical characters: indicate Gram stain, oxygen demand, utilization or decomposition of carbohydrate, utilization or decomposition of special substances, capacity for forming enzyme and toxin.
20. Metabolite: required for environmental sanitation.

Physical and chemical analysis or biological analysis

I. Sample name

II. Manufacturing date and lot number

III. Qualitative analysis

IV. Quantitative analysis

(1)Method

1. Apparatus, reagents
2. Analysis method
3. Calculated formula
4. Date analysis (include the analysis of diagram, but diagram is not required for tiltration method)
5. Error range

(2) Result of analysis

V. Microbial agents should additionally attach

(1) Incubation method

(2) Extraction method

Analysis report of active ingredients concentration

I. Sample name

II. Applicant’s name and address

III. Manufacturing date and lot number

IV. Permit number (not required for manufacturer without permit number)

V. Test institutions or units (signatures are required for examiner and supervisor)

VI. Sample submission

VII. Report date

VIII. Examination method

IX. Test result

Remarks: This analysis report can be substituted by the analysis report of examination and determination institutions (establishments), but have to cover above items.

Toxicology report

I. Summary

II. Report date

III. Examination title, quality and purpose

IV. Title and address of test institutions (Signatures are required for examiner and supervisor)

V. The date for initiating and completing the examination

VI. Foreword

VII. Test Substance

(1) Sample name
(2) Sample active ingredients concentration
(3) Sample manufacturing date and lot number
(4) Sample source
(5) Sample receipt date
(6) The sample status while receipted (package status, physical status)
(7) Applicant’s name and address

VIII. The name and character description of a comparison substance

IX. Examination method

(II) Animal testing method

1. Tested animals

(1) Animal’s source
(2) Animal’s name
(3) Amount
(4) Gender
(5) Age
(6) Weight (prior to test)
(7) Adjusting period
(8) Feeding conditions (include the observation frequency of temperature,

humidity, time period to turn on and turn off the light, food, drink water, atmosphere)

(9) Screening for animal test

2. Material, reagent, and composition of solution

3. Test method

(1) The time period of test

(2) Adjustment (preparation) of subject animal

(3) The way to dispense (apply) medicine

(4) Deliver dosage and method

(5) Time period and frequency to observe the health and death condition of animals

(6) Pharmacological and toxicological diseases time period

(7) Time period to measure animal's weight

(8) The treatment and record of animal after the test completed.

4. Test result

(1) Weight

(2) Pharmacological and toxicological symptoms

(3) Mortality

(4) Autoptic result

(II) Other examination methods (not required for manufacturers without animal testing method)

X. Conclusion

XI. Reference

XII. Appendix and attached table

Efficacy (potency) report

I. Sample name (state if there is foreign name)

II. Applicant’s name and address

III. Manufacturing date and lot number

IV. Permit number (not required for manufacturers without permit number)

V. Test institutions or units (Signatures are required for the examiner and host)

VI. Sample submission

VII. Report date

VIII. Formulation type and packing

IX. Sample active ingredients concentration

X. Chemical name

XI. Prevention subjects and methods suggested by applicant

XII. Test organisms and laboratory conditions

(1) Scientific name in Chinese and English
(2) Gender
(3) Age (in term of rat)
(4) Amount or number
(5) Laboratory conditions (temperature, humidity)

XIII. Test material and method (include dosage)

XIIII. Test frequency (repeat frequency) (should be triple conduction in rat comparison)

XV. Result [space-spray agent is knock-down time (KT_{50}, KT_{95}) and mortality (%), agent with flush-out effect is 50% flush-out time FT50; residual spray agent is mortality of 24 hours

and over 24 hours; pollution-preventive agent and microbial agent used in pollution prevention is removal rate of specific substance]

XVI. Conclusion (include discussion and suggestion)

Remarks:

1. Test frequency: list all data acquired during every repeat test.
2. The result of pollution-preventive agents and microbial agents used in pollution prevention is indicated by the removal rate of specific substance.
3. Discussion and suggestion: examiner address relevant suggested method and dosage after comparing the test result and method marked by applicant.
4. The efficacy report can be substituted by the original of examiner or the institute that established the efficacy report, and only have to cover above items.

Summary of manufacturing process (explanation of manufacturing flow chart)

I. Raw materials

II. Conditions
(1) Temperature
(2) Pressure
(3) Volume
(4) Catalyst

III. Equipments' name

IV. Accessories' name and manufacturing location (attached if apply for technicial grade environmental agents)

V. Manufacturing flowchart

Remarks: import permit application should attach the physical and chemical information provided by original manufacturer.

Product safety and quality control tests, and application and storage

I. Product safety and quality control test

(1) Leakage test (internal spray, and liquid product dose attached)

(2) Explosion (internal spray dose attached)

(3) Integrity of indication (representative method of manufacturing date and lot number)

(4) Time of use (mosquito coil, mosquito mat, mosquito liquid vaporizer does attached)

(5) Prevention of secondary pollution (environment, and human body)

II. Description of use and storage

(1) Equipment

(2) Influent factors (include use and storage)

1. Influence while temperature change
2. Influence while humidity change
3. Influence while time change

Remarks:

1. Equipment: not required for general use environmental agents and technical grade environmental agents, such as spray, mosquito coil, mosquito mat, mosquito liquid vaporizer, bait, liquid bait, granule, powder, smoker, fogger.
2. Import permit application should attach the application and storage provided by original manufacturer.

Instructions for pollution control

The name and localized manufacturing process location of pollution-preventive equipments in the manufacturing process.

Marking instruction

Marking items	Marking content
I. Model of written characters in environmental agent II. Warning or warning symbol III. Permit number IV. Product name V. Active ingredient and concentration VI. Performance VII. Formulation type and Packing VIII. Applicable range and method IX. Notice while use and storage X. Toxicosis symptom, first aid and detoxification method XI. The method to recycle and clean waste containers XII. Manufacturer's name, address, and telephone number XIII. Manufacturing date and lot number XIIII. Shelf life	

Remarks:

I. Warning or warning symbol

(1) The warning of "Do not spray this product on skin and clothes" should be marked on mosquito repellent.

(2) The warning "During prevention of fire ants, do not use this product on the soil around a cultivation zone, and crop and food processing area and place" should be marked on fire ants' preventive agents.

(3) "This product is limited to be applied by environmental agent manufacturer" should be marked on technical grade environmental agents.

(4) "This product is limited to be applied by environmental protection and health institution or its affiliated institutions, disease vector control enterprises or local approved of the competent authority" should be mark on restricted environmental agents usage.

II. Active ingredient and concentration:

(1) Active ingredient should mark Chinese name and English common name.

(2) The content of environmental sanitation agents should be represented by weigh percent (% w/w) or milligram (mg).

(3) The content of environmental microbial agents should be represented by Colony Forming Unit (CFU) and amount of Inclusion Body (IB) based on microbial amount; and represented by International Toxic Units (ITU) or International Units (IU) based on potency unit.

(4) The content of pollution-preventive agents should be represented by weigh percent (% w/w).

III. Performance: if mosquito coil, electric mosquito coil, liquid electric coil belong in the knock-down category, “this product only equip knock-down effect” or “this product is knock-down dose” must be marked on performance column.

IV. Method: the dilution multiple should be presented in the acquired efficacy report or efficacy information.

V. Toxicosis symptom, first aid and detoxification method: is eye irritant or dermal irritant must marked.

VI. Method of recycle and cleaning waste containers: should mark recycling channels, recycling marks, and package materials.

VII. Import permit application should attach one copy of the label of original manufacturing marking.

Application instructions for environmental agents

I. Application requirements:

(1) Fill out this application with Chinese typing; quote and reference with Chinese abstract typing; print (or copy) attached data as in double sided if possible.

(2) The unit of content is represented by metric system (such as g, kg, ml, and l).

(3) If there are quotations, the reference source and page number should be marked in this document, and submitted with the original text.

II. Application instructions for environmental agent permit:

(1) Application column: should mark application reason, and detailed modification items, such as alteration of performance or statutory responsible person(s) etc.

(2) Permit number column: not required for new application.

(3) Category column: mark "√" at appropriate blank space in front of environmental agents, pollution-preventive agents, or environmental microbial agents based on the category of environmental agents.

(4) Classification column: mark "√" at appropriate blank space in front of general use, restricted use, or technical grade based on the type of environmental agents.

(5) Chinese product name column: please apply with Chinese article, can not apply for the registration of an article that involve another person's trademark patent, lead to consumer's misunderstanding, misuse, or contain offensive article.

(6) Foreign product name column: the foreign article of import permit application should be filled out based on foreign article on manufacturing and selling certificate and franchise authorization. Application for product manufactured domestically does not require a foreign article, but if you want to fill out a foreign article, the foreign article can not be identical with registered foreign article.

(7) Formulation type classification is as follow: powder dose, moisturable powder dose, soluble powder dose, mosquito coil dose, granule dose (pastil, bulk, tablet, pill), fumigant, liquid dose, emulsion, water suspension, ultra-low volume dose, spray, electric mosquito coil dose, smoke agent, bait dose, and micro-capsule.

(8) Packing: detailed list each component, and please represent this unit by the metric system; product with minimum component should be integrally marked; the amount of application component are limited to maximum 10.

(9) Import permit application should mark based on the contents provided by original manufacturer, but can not mark and list randomly.

(10) Performance column: fill out the mouse and bug items if there is used for environment and sanitation prevention, fill out disinfect or sterilize if there is used as bactericide, or fill out prevention for air pollution, water pollution, soil pollution or wastage treatment.

(11) Components and contents column should be filled out with detailed component, and marked that each component is belong to effective component, synergist, emulsifier, coloring agent, antiseptic, solvent, excipient, or spice.

(12) The component content of microorganism and its metabolite is represented by CFU, IU, ITU, or IB/g, mg, or weigh percent (% w/w).

1. Toxins: International Toxic Units (ITU)

2. Virus: Inclusion Bodies (IB)

3. Bacteria, fungi: Colony Forming Units (CFU)

4. Enzyme: International Units (IU)

(13) The English name of component is an ISO name based on ISO nomenclature of International Organization for Standardization. If the International Organization for Standardization does not have a ISO name for this component, the component can be named based on IUPAC, BSI, or JMAF (please mark the nomenclature adopted). The article used by applicant can be added while necessary.

(14) Applicant basic information column: have to mark code number and zip code in the

information for contact person of application.

(15) Manufacturer column: the name and address of domestic manufacturers should be filled out by registered factory name and address. Importers have to fill out name, address and foreign factory address.

(16) There should be seal of applicant(s), responsible person(s), and professional technician(s) personnel, and information in this column should match with the attached certificate(s).