FORM A3

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A BIOCHEMICAL PEST CONTROL PRODUCT

Introduction

1. These guidelines are for any proposed use of the chemical products (growth regulators, pheromones, botanical products, e.t.c) of naturally occurring organisms (bacteria, protozoa, fungi, viruses, plants, animals, e.t.c) for the control of invertebrate pests and pathogens of crops and livestock, the control of weeds, public health and environment. **The use of biochemical pest control products for the control of vertebrate pests is not contemplated.**
2. Information in support of a request for registration, both published and unpublished should be supplied in the form of a summary data sheet laid out according to the format given in Form A3
3. A pre-registration consultation between the applicant and the registration authority is strongly recommended.

Information for Applicants

1. The application form must be completed by a person duly authorized by the applicant/company
2. The application must be submitted in triplicate to:
   The Secretary, Pest Control Products Board (PCPB) P.O. Box 13794, 00800 Nairobi.
   E-mail address: pcpboard@todays.co.ke/md@pcpb.or.ke Tel: 254- 020 - 4446115/4450242
   Fax: 254- 020- 4449072.
3. Every application must be accompanied by:-
   a) registration fee as prescribed.
   b) Three copies of the draft label as per PCPB requirements.
4. The applicant shall be required to submit:-
   a) a sample of the pest control product;
   b) a sample of the technical grade of its active ingredient.
   c) a sample of the laboratory standard of its active ingredient.
   d) any other sample as may be required by PCPB.
5. List I and II are supplied as check lists and an index to ensure that the applicant has provided all relevant data.
6. The application must be accompanied by a technical dossier as per PCPB data requirements i.e. Lists I and II
7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya.

PURPOSE OF APPLICATION (tick as appropriate)

a. Biochemical pest control products containing a new active ingredient	☐
b. Biochemical pest control products where source of active and/or formulation is not identical to that of a registered product	☐
c Registration transfer	☐
d. Amendments to existing registration	☐
e. Other (Explain) …… …… ……	

Will the product be marketed under own label Yes ☐ No ☐ If no, specify ……		

1. APPLICANT		
1.1 Identification		
Name of applicant / Corporate name of company		
Reg No.:		
Name of registration holder.		
Name of local agent in country: (if different from registration holder)		
1.2 Status: (Importer/formulator/ distributor) etc.		
1.3 Physical Address		
1.4 Postal Address:		
1.5 Telephone: (and area code)		
1.6 Fax: (and area code)		

2. PRODUCT			
2.1 Identity			
2.2 Concentration of a.i.			
2.3 Designation (Description of product)	Trade name:		
	Trade mark:		
	Trade mark holder:		
	Internal code:		
2.4 Function of product: (e.g. Insecticide, herbicide etc.)			
2.5 Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc.			
2.6 Target pest(s) and host(s)			
2.7 Method, dosage rates and frequency of application:			
2.8 Type of formulation: (e.g. EC, WP, etc.)			
2.9 Is the product registered in country of a) origin b) manufacture: c) formulation:	Yes ☐ No ☐ If no, specify …….. Yes ☐ No ☐ If no, specify …….. Yes ☐ No ☐ If no, specify ……..		
2.10 Registration in SEARCH** country/ies: (names)			
2.11 Registration in other country/ies, especially OECD countries: (names)			
2.12 Customs Tariff Code: (Brussels Tariff Nomenclature)			

* Formerly GCPF.
** SEARCH – Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration

3. COMPOSITION OF ACTIVE INGREDIENT(S) (Technical grade) (Information on a.i may be attached in sealed envelope)			
Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Minimum a.i.% purity	a.i. Range %

4.TOXICOLOGY OF ACTIVE INGREDIENTS (Technical grade)	Acute Oral (LD_{50} mg/kg)	Acute dermal (LD_{50} mg/kg)	Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental
5. FORMULATION	Calculated	Calculated	Calculated

5.1 Formulator: (Name)	Postal Address:
5.2 Internal code:	Physical address:

5.3 Composition (Information on composition may be attached in sealed envelope)

Ingredients and Function:	units	units	Range

6. TOXICOLOGY (formulated product)

6.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} g/kg)	Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated

6.2 Rabbit:	Skin irritation	Eye irritation
None		
Mild		
Moderate		
Severe		

6.3 Skin Sensitization in guinea pig (tick)	None ☐	Mild ☐	Moderate ☐	Severe ☐	
6.4 WHO classification:	Ia	Ib	II	III	Others

6.5Summary of other mammalian toxicological information may be required

6.6Summary of environmental effects

6.6.1Toxicity to bees:	
6.6.2Toxicity to fish and other aquatic organisms:	
6.6.3Toxicity to birds:	
6.6.4Toxicity to earthworms and soil microorganisms:	

6.6.5 Toxicity to other non-target organisms may be required:	
6.6.6 Persistence in environment:	
6.6.7Other effects: Specify	
7. PACKAGING	
7.1 Packaging material / container:	
7.2 Pack size(s):	
7.3 Disposal of empty container(s):	

8. OTHER SPECIFIC REQUIREMENTS

8.1 Operator exposure	
8.2 Dermal absorption.	
8.3 Likely operator exposure under field conditions	
8.4 Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).	
9. DECLARATION	
For and on behalf of …….. I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…….. Name in full (printed)	……. Signature
…….. Official Title	…… Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks …….. …….. …… …… …… …… Signed: Date:

NOTE: The format of this application form is recognized by all SEARCH countries.

FORM A3, LIST I

ACTIVE INGREDIENT: DOSSIER INDEX FOR BIOCHEMICAL PEST CONTROL PRODUCTS

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. i.e., details of the methods used and results of toxicological and ecotoxicological studies, methods of analysis, etc. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient/agent, compile a separate dossier for each active ingredient.

1. **DESIGNATION/IDENTITY OF a.i.**

ACTIVE INGREDIENT (Technical grade)	**Annex No. in dossier if study included**	**Official use only**
1.1 Common name (ISO)		
1.2 Chemical/scientific name		
1.3 Chemical group/classification		
1.4 Structural formula (if applicable)		
1.5 Empirical formula (if applicable)		
1.6 Manufacturer or Development code		
1.7 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.8 Methods of manufacture (synthesis pathways)		
1.9 Composition of the natural product before formulation		
1.10 Patent status		
a) Is the a.i./agent under patent		
b) Who is patent holder		
c) When was the product patented?		
d) Expiry date		
1.11 Molecular mass (if applicable)		
1.12 CAS Number (if applicable)		

2. PHYSICAL AND CHEMICAL PROPERTIES
(Active ingredient– technical grade)

2.1 Physical state (liquid, solid etc)		
2.2 Colour		
2.3 Odour		
2.4 Density at 20^{o}C (if applicable)		
2.5 Vapour pressure at 20/25^{o}C		
2.6 Volatility (if applicable)		
2.7 Hydrolysis DT_{50} ….. Days …… ^{0}C …… PH (if applicable)		
2.8 Photolysis		
2.9 Solubility in water ……^{0}C …….. PH (if applicable)		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient (if applicable)		
2.12 Boiling point ^{0}C (if applicable)		
2.13 Melting point ^{0}C (if applicable)		
2.14 Decomposition temperature ^{0}C		

2.15 Method of Analysis, active agent and Impurities/ contaminants		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products may be required.		
2.17 Stability in organic solvents used in formulation (if applicable).		
2.18 Stability in air; identity of breakdown products (if applicable)		
2.19 Thermal stability, identity of breakdown product.		
2.20 Flammability (if applicable)		
2.21 Flash point (if applicable)		
2.22 Explosive properties (if applicable)		
2.23 Oxidizing properties (if applicable)		
2.24 Absorption spectra – UV/Visible, infra-red, IMR, MS (at least two)		
2.25 Reactivity towards container material		

3. TOXICOLOGY
(Active ingredient – technical grade)

	Annex No. in dossier if study included	**Official use only**
3.1 Acute oral LD_{50} mg/kg rat/rabbit		
3.2 Acute dermal LD_{50} mg/kg rat/rabbit		
3.3 Inhalation LC_{50} mg/4 hour (rat)		
3.4 Skin irritation (rabbit)		
3.5 Primary eye irritation (rabbit)		
3.6 Skin sensitization (guinea pig)		
3.7 Reproduction		
3.8 Subchronic toxicity 90 day NOEL mg/kg/day (optional)		
3.9 Chronic toxicity NOEL mg./kg/day		
3.10 Carcinogenicity (life time) NOEL mg/kg/day (conditional for semiochemicals)		
3.11 Neurotoxicity NOEL mg/kg/day (conditional for semiochemicals)		
3.12 Teratogenicity NOEL mg/kg/day conditional for semiochemicals)		
3.13 Mutagenicity /Genotoxicity (conditional for semiochemicals)		
3.14 Metabolism (rat)		
3.15 Hypersensitivity/allergies in human		
3.16 Other studies		

4. ECO-TOXICOLOGY (Technical grade)
(Active ingredient – technical grade

	Annex No. in dossier if study included	**Official use only**
4.1 *Birds (2 species)	LD_{50} mg/kg	
	NOEL	
	Reproduction	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
4.2 *Fish (2 species)	LD_{50} mg/kg	
	NOEL	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
	BCF	
4.3 *Daphnia	LC_{50} mg/l	
	NOEL	
4.4 Algae	LC_{50} mg/l	
	NOEL	
4.5 *Bees	LD_{50} µg/bee	
	NOEL	
4.6 *Earthworms	LC_{50} mg/kg	
4.7 Soil micro-organism (if applicable)		
4.8 Others (e.g. plants)		

*** conditional requirement for semiochemicals.**

5. BEHAVIOUR IN ENVIRONMENT
(Active ingredient– technical grade)

	Annex No. in dossier if study included	**Official use only**
5.1 Behaviour, ways of degradation, degradation products in soil:		
5.11 Major metabolites		
5.12 DT_{50} (days)		
5.13 Mobility of a.i.		
5.14 Adsorption / desorption		
5.15 Mobility of metabolites		
5.2 Behaviour, ways of degradation, degradation products in water		
5.21 Major Metabolites		
5.22 DT_{50} (days)		
5.23 Surface water		
5.24 Ground water		
5.3 Behaviour, ways of degradation, degradation products in air.		

6. MODE OF ACTION

6.1 Mode of action of biochemical		

7. RESIDUES

	Annex No. in dossier if study included	**Official use only**
7.1 Major metabolites		
7.2 Metabolism		
7.3 Behaviour of residues		
7.4 Adsorption/absorption		
7.5 MRL codex		
7.6 MRL country of origin		
7.7 PHI, proposed MRL and ADI		
7.8 Method of residue analysis		

8. OTHER SPECIFIC REQUIREMENTS

	Annex No. in dossier if study included	**Official use only**
8.1 Residue data from a GLP certified laboratory or as directed by the Secretary PCPB.		
8.2 Proposed pre-harvest intervals, withholding periods in case of post-harvest use.		
8.3 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products.		
8.4 Effects on industrial processing and/or household preparation on the nature and magnitude of residues.		
8.5 Residue data in succeeding or rotational crops where presence of residues might be expected.		

FORMULATED PRODUCT: DOSSIER INDEX ON BIOCHEMICAL PEST CONTROL PRODUCTS

The dossier accompanying the form should provide more details of the information requested in this list. Summaries of the methods and results used in toxicological and ecotoxicological studies, methods of analysis etc. must be provided.
Numbering used in the dossier must correspond with that used in the application Form A3 LIST II

1. PHYSICAL AND CHEMICAL PROPERTIES

	Annex No. in dossier if study included	**Official use only**
1.1 Source and specifications for components included in the formulation		
1.2 Physical state (solid, liquid etc)		
1.3 Colour		
1.4 Odour		
1.5 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.6 Storage stability in proposed packaging		
1 7 Shelf life		
1.8 Density		
1.9 Bulk density		
1.10 Flammability		
1.11 Flash point		
1.12 Explosivity		
1.13 Compatibility with other pesticides		
1.14 pH		
1.15 pH of 1% aqueous dilution		
1.16 Oxidizing properties		
1.17 Corrosiveness		
1.18 Water content		
1.19 Wettability		
1.20 Solubility in water		
1.21 Solubility in organic solvents		
1.22 Partition coefficient n-Octanol		
1.23 Persistent foaming		
1.24 Particle size		
1.25 Wet sieve test		
1.26 Dry sieve test		
1.27 Suspensibility / emulsifiability		
1.28 Emulsion stability		
1.29 Volatility		
1.30 Viscosity		
1.31 Other properties		
1.32 Methods of Analysis		

Note: This information is required where applicable .

2. TOXICOLOGY

	Annex No. in dossier if study included	**Official use only**
2.1 Acute oral LD50 mg/kg (rat/rabbit)		
2.2 Acute dermal LD50 mg/kg		
2.3 Inhalation LC50 mg/l /4 hour		
2.4 Skin irritation (Rabbit)		
2.5 Primary eye irritation		
2.6 Skin sensitisation in guinea pig		
2.7 WHO classification		
2.8 Other studies (if applicable)		

3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING

	Annex No. in dossier if study included	**Official use only**
3.1 Symptoms of human poisoning		
3.2 Mode of action in man		
3.3 First aid treatment		
3.4 Skin contact		
3.5 Eye contact		
3.6 Inhalation		
3.7 Ingestion		
3.8 Antidote		
3.9 Note to physician		

4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE

	Annex No. in dossier if study included	**Official use only**
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. USES/EFFICACY DATA (New label claims with this application)

	Annex No. in dossier if study included	**Official use only**
5.1 Crop/area of use		
5.2 Target organism		
5.3 Rate of application		
5.4 Stage of treatment		
5.5 Directions for use		
5.6 Residue data, pre-harvest interval and ADI		
5.7 Phytotoxicity		
5.8 Contra indications		
5.9 Local biological efficacy data		

6. MINIMUM LABEL REQUIREMENTS – See requirements (provided separately)**.**

7. OTHER SPECIFIC REQUIREMENTS

	Annex No. in dossier if study included	**Official use only**
7.1 Medical surveillance, on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry, fisheries.		
7.3 Proposed packaging . Type of packaging in which the product is imported . Type of packaging for distribution in Kenya . Packaging material . Sizes of individual packaging		
7.4 Procedures of destruction and decontamination of pest control product and its packaging . Possibility of neutralization . Controlled discharge . Controlled incineration . Water purification . Procedures of cleaning application equipment . Recommended methods and precautions concerning handling, storage, display or transport.		

GUIDELINE: ACTIVE INGREDIENT DOSSIER FOR BIOCHEMICAL PEST CONTROL PRODUCTS

The dossier accompanying this form should provide details of the information requested. Methods used (physical and chemical), details of the methods used in and results of toxicological and ecotoxicological studies, methods of analysis etc. have to be given. Numbering used in the dossier must correspond with that used in the application form.

ACTIVE INGREDIENT (TECHNICAL GRADE)

1. DESIGNATION

REQUIREMENTS:	REMARKS:
1.1 Common name (ISO)	Indicate where applicable
1.2 Chemical/scientific name	State chemical name or full scientific name if applicable.
1.3 Chemical group/classification	State chemical group/classification.
1.4 Structural formula (if applicable)	Specify if applicable
1.5 Empirical formula (if applicable)	Specify if applicable
1.6 Manufacturer or Development code	Specify Source/manufacturer.
1.7 Source, Name and address of manufacturer and address and location of manufacturing plants.	Source: Natural occurrence and geographical destribution For botanicals specify the plant part, stage of growth etc. Name, address, location of manufacturing plant.
1.8 Methods of manufacture(synthesis pathways)	Manufacturers to outline how the product is produced in bulk, quality assurance, for manufacturing process, assay methods, Isolation, culturing of microbial agents if derived from a live organism.
1.9 Composition of natural product before formulation	Give the composition of the active ingredient, methods of identification and purity of active ingredient Evidence to show freedom from microbial contamination, nature and identity of any impurities should be provided.
1.10 Patent status	Specify
a) Is the a.i./agent under patent?	
b) Who is patent holder?	
c) When was the product patented?	
d) Expiry date	
1.11 Molecular mass (if applicable)	
1.12 CAS Number (if applicable)	

2. PHYSICAL AND CHEMICAL PROPERTIES (active ingredient – technical grade)

REQUIREMENTS	REMARKS
2.1 Physical state	Powder, liquid or solid
2.2 Colour	Specify If applicable
2.3 Odour	
2.4 Density at 20^{o}C	
2.5 Vapour pressure at 20/25^{o}C	
2.6 Volatility	
2.7 Hydrolysis/persistence	Give the DT_{50} of the active ingredient, with mention of temperature and pH parameters employed during the determination, include retention of biological activity in storage and in the field.
2.8 Photolysis	Give the DT_{50} of the active ingredient (in days).

2.9 Solubility in water	Where relevant indicate method/test used.
2.10 Solubility organic solvents	Where relevant indicate methods/test used
2.11 n-octanol/water partition coefficient	
2.12 Boiling point ^{o}C	
2.13 Melting point ^{o}C	
2.14 Decomposition temperature ^{o}C	
2.15 Method of Analysis and Impurities	
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products	Provide information with evidence
2.17 Stability in organic solvents used in formulation	
2.18 Stability in air; identity of breakdown products	
2.19 Thermal stability, identity of breakdown product.	
2.20 Flamability	
2.21 Flash point	
2.22 Explosive properties	
2.23 Oxidizing properties	
2.24 Absorption spectra – UV/Visible, infra-red, IMR, MS	
2.25 Reactivity towards container material	

Note: Provide information where applicable.

3. TOXICOLOGY
(Active Ingredient – technical grade)

Include a copy of an executive summary discussing **ALL ISSUES** named under section 3 of the form or provide copies of the individual summaries from each study relating to issues mentioned under section 3 of the form. Information on the methods of testing used must be provided.

REQUIREMENTS:	**REMARKS:**
3.1 Acute oral LD_{50} mg/kg rat/rabbit	Provide evidence
3.2 Acute dermal LD50 mg/kg rat/rabbit	
3.3 Inhalation LC_{50} mg/4 hour (rat)	This should be provided for the technical grade for all kinds of biochemicals
3.4. Skin irritation (rabbit)	
3.5 Primary eye irritation	Hazards associated with single application or associated with inert ingredients in product formulation.
3.6 Skin sensitization (guinea pig)	Provide relevant information
3.7 Reproduction	Provide relevant information
3.8 Subchronic toxicity 90 day NOEL mg/kg/day	Provide relevant information
3.9 Chronic toxicity NOEL mg./kg/day	Provide relevant information
3.10 Carcinogenicity (life time) NOEL mg/kg/day	Provide relevant information.
3.11 Neurotoxicity NEOL mg/kg/day	

3.12 Teratogenicity NOEL mg/kg/day	Provide relevant information.
3.13 Mutagenicity /Genotoxicity	
3.14 Metabolism (rat)	
3.15 Hypersensitivity/allergies in human	
3.16 Other studies	

NB - Botanical preparations should be free from mycotoxins. (An analytical proof is required.
- Allergenic potential of pest control products should be investigated and provided.

Other studies:

Provide further information relevant to the toxicity profile of the product e.g. toxicity of major metabolites, reaction or breakdown products of the pest control product, formed in/or on treated plant/crop etc, which are likely to be consumed in cases where different from those identified in animal studies. Toxic effects on livestock, poultry, pets should be stated.

4. ECO-TOXICOLOGY

Provide either an executive summary or individual summaries of studies on the behaviour in the environment providing information requested in the form.

REQUIREMENTS:	**REMARKS:**	
4.1 Birds (2 species)	LD_{50} mg/kg	Provide details of at least one land and one water bird, LD_{50} in mg product/kg bird weight and the NOEL. Furthermore provide information on the effect on reproduction.
	NOEL	
	Reproduction	
	LD_{50}mg/kg	
	NOEL	
	Reproduction	
4.2 Fish (2 species)	LD_{50} mg/kg	Provide details on at least two species studied, LC_{50} (in mg of product / litre of water) and the NOEL. Furthermore provide information on the effect on reproduction. Indicate the bioconcentration factor (BCF) on the active ingredient in tissues.
	NOEL	
	Reproduction	
	BCF	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
	BCF	
4.3 Daphnia	LC_{50} mg/l	Specify and provide details on other organisms according to the information requested on the form.
	NOEL	
4.4 Algae	LC_{50} mg/l	
	NOEL	
4.5 Bees	LD_{50} µg/bee	
	NOEL	
4.6 Earthworms	LC_{50} mg/kg	
4.7 Soil micro-organisms		
4.8 Others e.g. plants		If the agent is closely related to a crop pathogen or a pathogen of a vertebrate, species, laboratory evidence of genetic stability using appropriate tests is required.

5. BEHAVIOUR IN ENVIRONMENT (Active ingredient– technical grade)

Provide an executive summary or copies of summaries from each study relating to the issues highlighted in this application form.

REQUIREMENTS:	REMARKS:
5.1 Behaviour, spread, mobility, multiplication ways of degradation, degradation products in soil:	**Indicate the degradation path of the active ingredient in the soil and the degradation products formed.**
5.11 Major metabolites	Specify the major metabolites/ residues in the soil and their behaviour.
5.12 DT_{50} (days)	Specify the half-life of the active ingredient in various types of soils. Or persistence, retention of biological activity.
5.13 Mobility of the a.i.	Specify the degree of mobility of the active ingredient in the soil hence leaching potential and possibility for ground water contamination. If high, provide details on further studies i.e. lysimeter study.
5.14 Adsorption / desorption	Indicate the degree of adsorption of the active ingredient in the soil.
5.15 Mobility of metabolites spread, mobility, multiplication.	Indicate the degree of mobility of the metabolites/ residues in the soil.
5.2 Behaviour, ways of degradation, degradation products in water:	**Describe ways and speed of degradation of the active ingredient/agent in water.**
5.21 Major Metabolites	Specify the major break down products formed and their adsorption/desorption on sediments.
5.22 DT_{50} (days)	Specify the half life of the active ingredient in water
5.23 Surface water	Describe ways and speed of degradation in surface and ground water.
5.24 Ground water	
5.3 Behaviour, ways of degradation, degradation products in air:	**Describe ways and speed of degradation in air and break down product formed (for fumigants and volatile products). Provide an executive summary of the studies conducted.**

6. MODE OF ACTION:

6.1 Mode of action of biochemical	Explain the mechanism by which the pest control product acts on the target organism, degree of specificity

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7. RESIDUES

Provide either an executive summary or individual summaries of studies conducted concerning the issues listed.

REQUIREMENTS:	REMARKS:
7.1 Major metabolites	Provide either an executive summary or individual summaries of studies conducted concerning the issues listed. . Specify the metabolites/ residues . State their toxicological effects. . Retention of microbial activity.
7.2 Metabolism	Describe the principle of metabolization of the active ingredient/agent in the plant and the degradation products formed.
7.3 Behaviour of residues	Indicate the action and the persistence of the metabolites/ residues in the plants and animals.
7.4 Adsorption/absorption	Provide either an executive summary or individual summaries of studies conducted by a GLP certified laboratory or as directed by the Secretary PCPB.
7.5 MRL codex	MRL's (if available) When available state for each crop or vegetable product, the Maximum Residue Limit (MRL) recommended by the Codex Alimentarius Commission, two effective MRL's in two different countries and the MRL proposed in the country of application. If the proposed crop is to be exported, provide detailed information in the dossier on MRL levels or import tolerances in the countries exported to. Provide information on ADI. Provide information on method of residue analysis.
7.6 MRL country of origin	
7.7 PHI, proposed MRL and ADI	
7.8 Method of residue analysis	

Residue data has to be provided for bioproducts if they are found to have toxicological, infectivity and pathogenicity concerns to mammals.

8. OTHER SPECIFIC REQUIREMENTS

REQUIREMENTS:	REMARKS:
8.1 Residue data from a GLP certified laboratory or as directed by Secretary, PCPB	Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
8.2 Proposed pre-harvest intervals, withholding periods in cases on post-harvest use.	
8.3 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products.	
8.4 Effects of industrial processing and/or household preparation on the nature and magnitude of residues.	
8.5 Residue data in succeeding rotational crops where presence of residues might be expected.	

***** For pest control products found to have allergenic effects, detailed studies (on their residues have to be provided.

GUIDELINE: FORMULATED PRODUCT DOSSIER FOR BIOCHEMICAL PEST CONTROL PRODUCTS

1. PHYSICAL AND CHEMICAL PROPERTIES OF THE FORMULATED PRODUCT.

Clearly state method used to determine properties under the appropriate section of the dossier. CIPAC methods are recommended.

REQUIREMENTS:	REMARKS:
1.1 Source and specifications for components included in the formulation.	Specify
1.2 Physical state	Specify (Solid, liquid, etc.)
1.3 Colour	Specify
1.4 Odour	Specify
1.5 Effects of light, air, temperature, water on technical characteristics of the formulation.	Provide information with evidence.
1.6 Storage stability in proposed packaging	Indicate the stability of the preparation after storing at 54^{o}C for 14 days. Other durations and/or other temperatures (e.g. 8 weeks at 40^{o}C, 18 weeks at 30^{o}C) if the preparation is thermo-sensitive.
1.7 Shelf life	The shelf life of the product at room temperatures (30^{o}C) is given in years if it is more than two years, and in months if it is less than two years; the appropriate temperature specifications must be given. Indicate how the shelf life was determined.
1.8 Density (Where applicable)	Indicate the density of the liquids.
1.9 Bulk density	Indicate the density of solids after compression.
1.10 Flammability	Specify if the product is flammable
1.11 Flash point	To determine flammable hazards.
l.12 Explosivity	Provide information.
1.13 Compatibility with other pesticides	Indicate types of pest control products which the product is or is not compatible with. Give evidence.
1.14 pH range	State the effect of pH on stability and effectiveness.
1.15 pH of 1% aqueous dilution	Relevant to products to be diluted in water.
1.16 Oxidizing properties	Indicate materials that can be damaged by oxidizing properties of the formulation.
1.17 Corrosiveness	Specify effect on containers, equipment, skin etc. If any.
1.18 Water content	Indicate the maximum water content when it has an influence on the quality.
1.19 Wettability	The wettability has to be indicated for solid formulations used in dilution (wettable powders, powder soluble in water and granules soluble in water).
1.20 Solubility in water	Specify
1.21 Persistent foaming	State the extent foaming occurs for formulations diluted in water.
1.22 Particle size	Specify
1.23 Wet sieve test	If applicable provide evidence.
1.24 Dry sieve test	

1.25 Suspensibility / emulsifiability	Specify.
1.26 Emulsion stability	Specify
1.27 Volatility	Specify
1.28 Viscosity	For formulations to be used at very low volume, it is necessary to know the viscosity.
1.29 Other properties (where applicable)	FAO specifications etc.
1.30 Method of Analysis	Specify

Other studies

Provide detailed studies on any other relevant toxicological or ecotoxicological studies conducted on the formulated product.

2. TOXICOLOGY

The dossier must contain a detailed Material Safety Data Sheet. Furthermore either an executive summary discussing all aspects mentioned under section 2 must be included, or the summaries from each individual toxicity study and field in the same order.

REQUIREMENTS:	**REMARKS:**
2.1 Acute oral LD_{50} mg/kg rat/rabbit	Provide evidence
2.2 Acute dermal LD50 mg/kg rat/rabbit	
2.3 Inhalation LC_{50} mg/4 hour (rat)	This should be provided for the technical grade for all kinds of biochemicals
2.4 Skin irritation (rabbit)	
2.5 Primary eye irritation	Hazards associated with single application or associated with inert ingredients in product formulation.
2.6 Skin sensitization (guinea pig)	Provide relevant information
2.7 WHO classification	See table below
2.8 Other studies	Indicate any other studies

NB - Botanical preparations should be free from mycotoxins. (An analytical proof is required.
- Allergenic potential of pest control products should be investigated and provided.

The FAO/WHO class must be given as per the table hereunder.

WHO-Classification Scheme

Class	LD50 for the rat (mg/kg body weight)			
	Solids	Liquids	Solids	Liquids
	Oral		Dermal	
Ia Extremely Hazardous	5 or less	20 or less	10 or less	40 or less
Ib Highly hazardous	5-50	20-200	10-100	40-400
II Moderately hazardous	50-500	200-2000	100-1000	400-4000
III Slightly hazardous	Over 500	Over 2000	Over 1000	Over 4000
Others				

3. EMERGENCY MEASURES IN CASES OF ACCIDENTAL EXPOSURE OR POISONING

Self explanatory. List relevant information of the form and refer to particular section in Material Safety Data Sheet(MSDS) in section 3 of dossier.

4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE

Self explanatory. List relevant information of form and refer to particular section in MSDS in section 2 of dossier.

5. USES/EFFICACY DATA (New label claims with this application)

REQUIREMENTS:	**REMARKS:**
5.1 Crop/area of use	The common name of the crop on which the product is aimed must be clearly specified. When the product is not aimed at a crop, indicate the area of use, e.g. Premises and equipment of transportation, Premises of storage.
5.2 Target organism	Target organisms must be identified by common and scientific name. Specify the mode of action of the product on its target, and indicate if the active ingredient is translocated inside the organism.
5.3 Rate	The rate of application of the product must be indicated on the basis of area treated or volume used e.g. l/ha, g/ha, etc.
5.4 Stage of treatment	Specify the stage of the crop and target organism at which application must be made and/or the minimum interval between the last application and harvest.
5.5 Directions for use	Indicate the recommended directions for use.
5.6 Residue data, pre-harvest interval, and ADI	Indicate restrictions for MRL and ADI
5.7 Phytotoxicity	Indicate restrictions.
5.8 Contra-indications	Indicate restrictions i.e. follow up crops, adjacent crops etc. and particular specifications, as well as possible incompatibilities of the formulation with other products.
5.9 Local biological efficacy data	To be generated in PCPB accredited institutions only

NB: Efficacy data from country of origin should be attached.

6. MINIMUM LABEL REQUIREMENTS

Specify the warnings, use restrictions and safety precautions which must be present on the label in all countries.
The proposed label must be included in the dossier, should contain the specified warnings, use restrictions and safety precautions as well as meet PCPB label requirements.
PCPB label requirements will be provided separately.

7. OTHER SPECIFIC REQUIREMENTS

	REMARKS
7.1 Medical surveillance, on manufacturing plant personnel	Provide details
7.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry, fisheries.	Provide details
7.3 Proposed packaging . Type of packaging in which the product is imported . Type of packaging for distribution in Kenya . Packaging material . Sizes of individual packaging	Provide details
7.4 Procedures of destruction and decontamination of pest control product and its packaging . Possibility of neutralization . Controlled discharge . Controlled incineration . Water purification . Procedures of cleaning application equipment . Recommended methods and precautions concerning handling, storage, display or transport.	Provide details

LIST OF ABREVIATIONS

a.i.	Active Ingredient
ADI	Acceptable Daily Intake
BCF	Bio Concentration Factor
CFU	Cell Forming Units
CIPAC	Collaborative International Pesticides Analytical Council
CLI	Crop Life International
DT_{50}	Time it takes for 50% of the parent compound to disappear from soild or water by transformation (half life).
EC	Emulsifiable Concentrate
EC_{50}	Median Effective Concentrate
FAO	Food and Agriculture Organization of the united nations
g/kg	Grams per Kilogram
g//	Grams per litre
GCPF	Global Crop Protection Federation
ISO	International Standards Organisation
IUPAC	International Union of Pure and Analytical Chemists
LC_{50}	Median Lethal concentrate
LD_{50}	Median Lethal Dose
mg/l	Milligrams per litre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NOEL	Non Observable Effective Level
OB	Occlusion Body
^{o}C	Degrees centigrade
PCPB	Pest Control Products Board
PHI	Pre Harvest Interval
SEARCH	Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration .
μg	Microgram
WHO	World Health Organization
WP	Wettable Powder
GLP	Good Laboratory Practice