Pest Control Products Regulations 2022

Pest Control Products (Registration) Regulations, 2022
S.15 (b, c, l)

The Pest Control Products Act is amended by the repeal of Pest Control Products (Registration) Regulations (LN 46, 109 of 1984, LN 123 of 2006, LN 122 of 2014, LN 124 of 2015) and their replacement with the following new regulations-

PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2022

ARRANGEMENT OF REGULATIONS

SCHEDULES

FIRST SCHEDULE**– FORMS**

SECOND SCHEDULE – ITEMS EXEMPTED FROM REGISTRATION

1. **Citation**
   These Regulations may be cited as the Pest Control Products (Registration) Regulations, 2022.

2. **Interpretation**
   In these Regulations, unless the context otherwise requires—

"designated competent persons" means a person or an institution that has been officially recognized by the Boardas having the capacity and competence to undertake biological efficacy trials, physicochemical studies, toxicological, ecotoxicological and residue studies;

"certificate of registration" means a certificate issued by the Boardunder regulation 7(4);

"device" means any article, instrument, apparatus, contrivance or gadget that by itself or in conjunction with a pest control product is used as a means to control pests directly or indirectly;

"national collection number" means the unique code given to a culture or an isolate by the National Museums of Kenya or any other institution recognized by the Board;

"parallel/daughter registration" means a registration of a trade name based on the strength of a registered product from the same manufacturer and source and with authorization from the registrant;

"registrant" means the owner of technical information submitted for the purposes of registration of a pest control product or person authorized in writing by such owner;

"biochemical pesticide" means a pest control product whose active ingredient constitutes a chemical derived from naturally occurring plant, animal or other organism intended to control invertebrate pests;

"Confidential Business information" (CBI) means the following:

- information that discloses manufacturing or quality control processes and 5-batch analysis

- information that discloses methods for testing and measuring the quantity of deliberately added inert ingredients and impurities
- information that discloses the identity or percentage quantity of deliberately added inert ingredients in the technical grade or formulated product

"experimental permit" means a permit issued by the Board for small quantity of a pest control product imported or produced locally for purposes of research, efficacy trials and other studies prior to consideration for registration;

"microbial and microbial biopesticide" means a pest control product of naturally occurring micro-organisms (microbiological agents such as viruses and rickettsia, bacteria, protozoa, fungi,) and macro-organisms (macro-biological agents such as predators, parasitoids and entomopathogenic nematodes), respectively intended for the control of invertebrate pests, weeds, pathogens of crops and pests of public health and to which effects of the pest control products or active agent are attributed but does not include a component that by itself is not primarily responsible for the control effect of the pest control product or genetically modified living micro-organism and macro- organism;

3. **Application for registration of pest control products**

(1) Pre-registration consultations between the applicant and the registration Board may be undertaken before the application has been made.
(2) Every person desiring to register a conventional pest control product shall make an application to the Board as per the guidelines for data requirements for registration of Conventional Chemicals under EAC as set out in Form A1 in First Schedule
(3) Every person desiring to register a biopesticide or a biocontrol agent shall make an application to the Board as per the EAC harmonized guidelines for registration of biopesticide and biocontrol agent as set out in Form A2 in First Schedule
(4) Every person desiring to register a generic pest control product equivalent to a registered product shall make an application to the Board using Form A3.
(5) Every person desiring to register a spray adjuvant, pest control product for use in paint for in-can and film preservatives, or a plant growth regulator and post-harvest product for flowers and ornamentals shall make an application to the Board using A4, A9, and A10,respectivelyas set out in the Second Schedule and shall on request submit any further information which may be required by theBoard.
(6) An applicant whose product is sourced from a non-English speaking country shall provide a translated registration certificate certified to be correct by recognized translators.
(7) A person who submits wrongly translated certificates or false documents shall be required to submit the dossiers afresh, pay introductory fee, conduct efficacy trials afresh
(8) The application for registration of a pest control product under Regulation 3(2)

to 3(5) shall be in the prescribed relevant Form completed by the applicant or duly authorized person and submitted in triplicate.

(a) The guidelines shall contain check lists and an index to ensure that the applicant has supplied the relevant data required in the Second Schedule.

(b) An applicant shall provide Information in support of a request for registration of biopesticides, both published and unpublished (fully cited) shall be supplied in the form of a summary data sheet as required in the EAC harmonized guidelines for registration of biopesticide and biocontrol agent.

(c) All applicants intending to import/export live organisms into or out of the country shall provide to the Boardproof of compliance with any other existing laws governing such organisms.

(d) An applicant intending to introduce genetically modified organisms and living modified organisms as microbial biopesticides shall provide to theBoard proof of compliance with any other existing laws governing such organisms before an application is made to the Board.

(e) An applicant intending to introduce microbial or microbial biopesticideshall be required to—

(i) submit a sample of the pest control product to the National Museums of Kenya;

(ii) submit to the Board a copy of the National Collection Number from the National Museum of Kenya;

(iii) provide a sample of the technical grade of its active agent to the Board;

(iv) send an additional sample to the National Agricultural Research Laboratories [KALRO-NARL], Biological Control Unit, Muguga (Kenya Agricultural & Livestock Research Organization), and Kenya Plant Health Inspectorate Service;

(v) supply any other sample as may be requested by the Board.

(9) For purposes of regulation 3(1) to 3(5) local efficacy trials shall be conducted following the EAC guidelines on generating and reporting of pest control products for plants and the national efficacy trial guidelines for public health products accordingly.

(10) For purposes of regulation 3(1) to 3(5) local efficacy data shall be generated as per the data extrapolation guidelines provided by the Board from time to time.

(11) For purposes of regulation 3(1) to 3(5) residual data for edible crops shall be generated and submitted following the EAC guidelinesfor the conduct of supervised pesticide residue field trials on crops.

(12) For purposes of regulation 3(1) to 3(5) residue data for edible crops shall be submitted or generated for an individual crop or indicator crop as per the data extrapolation guidelines provided by the Boardfrom time to time.

(13) For the purpose of this regulation, guidelines and forms shall include forms and guidelines adopted from East African Community and other Regional Economic Block(s) to which Kenya is a party

(14) The Board may upon determination that the active ingredient of the applicants' pest control product is equivalent to the active ingredient of a registered pest control product shall, subject to and in accordance with the regulations hereunder, waive some data required for the active ingredient and register the product upon submission of data for the formulated product.

(15) (a) The Boardmay upon such terms and conditions as it may specify andon payment of the introductory and application for registration fees, register a parallel/daughter pest control product where the applicant

(i) completes application the relevant registration form set out in the SecondSchedule;
(ii) provides a letter of access from registrant;
(iii) providesa letter of no objection from the local agent;
(iv) uses approved label of the original registered product and only changes the trade name.

(b) Each parallel/daughter registration shall have its own registration number, which shall be linked to the original registered product by indicating the original registered product number on the parallel registration certificates.

(c) Voluntary cancellation of a product shall apply to the registered product and the parallel/daughter products.

(d) The application for which a product is registered may change without affecting the parallel/daughter registration and may transfer access of the original dossier thereto.

(e) The parallel/daughter registration shall be automatically revoked when the registrant withdraws the letter of access.

(f) The parallel/daughter registration shall not be used to register other different products.

(g) A new dossier shall not be required for the registration of the parallel/daughter products;

(h) The original registered product and the parallel/daughter registration shall be required to originate from the same source.

(i) Parallel/daughter registrations shall be exempt from local efficacy trials if the intended use is identical to that of the original registered product.

(j) Efficacy trials shall be undertaken where new uses are different from those of the original registered products.

(k) The Board shall exercise discretion in determining the number of parallel/daughter products to be registered on a case-by-case basis but not

more than five such products shall be registered in respect of one original product.

(16) TheBoard may, upon such terms and conditions as it may specify, extend the use of a registered pest control product through a label extension where the applicant submits-

(a) successful two-season efficacy trial data on the respective area of use such as crop or pest combination as per the EAC Efficacy guidelines or National efficacy guidelines where applicable;

(b) residue data based on the Good Agriculture Practice in the efficacy trial, if the new use is on edible crops as per the EAC Residual guidelines or National Residue guidelines where applicable;

(c) a copy of the previously approved label;

(d) revised commercial label with the proposed new uses, rates, pre-harvest interval and re-entry interval and the final commercial version label;

(e) proposed maximum residue limits and pre- harvest intervals for edible commodities and re-entry interval for greenhouse use.

(17) (a) The application for registration of pest control products shall be accompanied by a copy of a summary dossier as prescribed in-

(i) Form B for conventional pest control products;
(ii) Form B1 for microbial pest control products;
(iii) Form B2 for macrobial pest control products;
(iv) Form B3 for biochemical pest control products other than semiochemicals;
(v) Form B4 for semiochemicals;
(vi) Form B5 for paint for In-Can and film preservatives;
(vii) Form B6 for post-harvest pest control products.

4. **Applicant for non resident**

(1) An applicant who is not resident in Kenya shall appoint, not more than one agent for the same product, who is a permanent resident of Kenya,

(2) The local agent shall;

(a) Have technical expertise in pesticide management or shall appoint a person with technical expertise in pesticide management

(b) facilitate registration, importation, exportation, product stewardship,

(c) be the contact person to whom any notice or correspondence relating to the pest control product may be sent,

(3) An applicant who is not resident in Kenya shall be required to deposit with the

Board a binding agreement with a clear duration of contract entered with the agent permanently resident in Kenya.

(4) An application for registration of an agent shall be submitted in **FormA5**set out in the Second Schedule.

(5) An application for registration for change of an agency shall be submitted in **Form A6**set out in the Second Schedule.

(6) Where either registrant or the local agent intends to terminate or change agency either party shall issue a six month notice to the other party copied to the Board

(7) Any person who fails to comply with the provisions of this regulation commits an offence

5. **Label to accompany application**

(1)An application for the registration of a pest control product shall be accompanied by a copy of the proposed label for the pest control product

6. **Technical information required**

(1)Every person desiring to introduce a pest control product for efficacy testing and other studies shall—

(a) supply any further information including regulatory data and confidential business information which may be required by the Board; and

(b) pay the prescribed application fees determined by the Boardfrom time to time therefore.

(c) The Boardshall evaluate the data provided and if satisfied that the application merits approval, shall issue an experimental permit in the prescribed Form C in the Second Schedule.

(d) The Board shall make available to the applicant information relating to the existing designated competent persons in the field of trial or study whom the applicant will work with.

(2) When the efficacy trials or other studies are complete the designated competent persons shall submit reports to the Board**.**

7. **Confidential Business Information**

(1) The Board, the registrant/ applicant and local agents shall put measures to protect confidential business information (CBI).

(2) All applications for registration of a pest control product shall be accompanied with detailed CBI as stipulated in Form D1 in the schedule.

(3) The EAC guidelines for protection of confidential business information submitted for pesticide registration action in the EAC partner states shall be

applicable.

(4) The applicant shall ensure that all CBI is submitted to the Board in a secure manner and by a responsible person, authorized by the Registrant.

(5) The applicant shall package and submit CBI in a sealed envelope or file separated from the other regulatory data clearly marked "Confidential Business Information"

(6) The local agent submitting the CBI shall sign confidential declaration, Form D2 at the time of dossier submission.

(7) An Officer of the Board receiving the CBI shall record the list of CBI data submitted in Form D1 in the first schedule.

(8) The Board shall store the CBI in a secure place and only allow access to authorized persons.

(9) On occasions it may be necessary to reveal to the Board or its committees or in court proceeding, tribunal/ hearings or in findings of fact issued by the Board, formulas of products, even if confidential, to carry out other provisions of the Board, e.g., in cancellation or suspension hearings.

(10) Information received that is marked "confidential business information" must not be copied unless authorized by the Board.

(11) The authorization to make copies must contain the following information:

(a) The name of the recipient of the copy.

(b) The intended purpose for which the copy is to be used.

(c) The manner in which the copy is to be disposed of after use.

(12) Any person who discloses Confidential Business Information contrary to this Regulation commits an offence

8**. Submission of samples**

(1) An applicant shall, when requested to do so by the Board, provide—

(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; and

(d) any other sample as may be required by the Board.

(2) The samples shall be submitted to the Board as set out in **Form A7**in the

Second Schedule.

9. **Denaturation**

Wherethephysicalpropertiesofapestcontrolproductaresuchthatthepresenceofthe pestcontrolproductmaynotberecognizedwhenitisused,andislikelytoexposeaperson or domestic animal to a severe health risk, the pest control product shall be denatured by meansofcolour,odourorsuchothermeansastheBoardmayapprovetoprovidesignal or warning of its presence.

10. **Fees for application for registration**

The fees payable by an applicant for the registration of a pest control product shall be the prescribed fees determined by the Boardfrom time to time.

11. **Issue of certificate of registration**

(1) The applicant shall submit the proposed trade name for consideration by the Board.

(2) The trade name in sub-regulation (1) may be changed upon request to the Board in **Form A8** set out in the Second Schedule.

(3) The Board shall conduct hazard and risk assessment on a pest control product and where applicable provide mitigation measures.

(4) The Board shall, if satisfied of the quality, safety, efficacy and economic value of the pest control product, shall register the pest control product, and issue a certificate of registration which shall be in **Form E** set out in the Second Schedule.

(5) If the Board is not satisfied as to the safety, efficacy, quality and economic value of the pest control product, the Board may after providing an opportunity for the applicant to be heard, reject the application for the registration of the pest control product and inform the applicant the reasons for the rejection in writing.

(6) No person to whom a certificate of registration has been issued under this Regulation shall lend, hire, sell, transfer or otherwise dispose of the certificate to any other person without the approval of the Board, which approval shall be endorsed on the certificate of registration.

12. **Duration and renewal of certificate of registration**

(1) A certificate of registration issued under these Regulations shall, unless earlier suspended or revoked, be valid for a period of five years from the date of issue and may thereafter be renewed for periods not exceeding three years at any one time.

(2) The fee for the renewal of a certificate of registration shall be the prescribed fees determined by the Board from time to time, and an application for renewal shall be accompanied by three copies of the current label for the pest control product.

(3) A holder of a certificate of registration who does not apply for renewal within six months after expiry of the validity period shall have the certificate suspended and have the pest control product removed from the list of registered products

(a) Where a certificate of registration has been suspended under sub-regulation (3) the suspension shall be lifted upon payment of requisite fees within a period of two

years.

(b) Where a certificate of registration has been suspended under sub-regulation (3) for two years without renewal, the registration shall be cancelled without further notice.

(4) A holder of a certificate of registration issued under these Regulations shall give a notice to the Board in writing at least 3 months before the expiry of the registration of any intentions to keep the product registration in abeyance for a period not exceeding 5 years and the notice shall—

(a) give reasons for temporary withdrawal; and

(b) show the records of all quantities of the pest control product in stock, manufactured and sold by holder of certificate of registration in last two years.

(5) The Board shall consider the notification under sub-regulation (4) and if satisfied with the reasons for temporary withdrawal shall suspend the registration of the pest control product for a period not exceeding 5 years.

(6) The information on suspended registration under sub-regulation (4) shall be made known to the holder in writing.

(7) A person whose certificate of registration has been suspended under sub-regulation (4) shall withdraw the product from the market within a period of 6 months from the date of suspension of registration.

(8) A person whose certificate of registration has been suspended under sub-Regulations (4) shall give a notice to the Board in writing of any intentions to reintroduce the product registration and the notice shall—

(a) give reasons for reintroduction;

(b) be accompanied by a fee for the renewal of a certificate of registration including the period that the product was in abeyance;

(c) be accompanied by three copies of the label conforming to legal requirement for the pest control product.

(9) A holder of a certificate of registration who does not apply for renewal within five years in accordance with sub regulation (8) shall have the registration cancelled and shall apply afresh and shall, on request supply any further information, which may be required by the Board.

13. **Temporary registration**

(1) The Board may upon such terms and conditions as the Board may specify, on payment of a prescribed fee determined by the Boardfrom time to time, register a pest control product for a period of one year renewable twice only where—

(a) the applicant agrees to produce additional scientific or technical information in relation to the use for which the pest control product is to be sold;

(2) Any terms and conditions specified by the Board under paragraph (1) shall be contained in the temporary certificate of registration.

14. **Emergency Registration**

The Board may upon such terms and conditions register a pest control product for

managing invasive and exotic pests for a period of one year renewable where there is localized, confined, nationwide invasion or infection or an emergency situation that can potentially affect plants or public health as the Board may specify.

(1) The applicant shall formally apply for an emergency use registration with the following documents:

(a) Written application form
(b) Proof of payment for application of emergency use application
(c) Supporting technical data on pest control product
(d) Product label
(e) Proof of registration in another country and any other additional information that the Board may require.

(2) The pest control product is to be sold only for the emergency control of infestations that are seriously detrimental to public health, animals, crops, agricultural produce or natural resources.

(3) The Board may cancel an emergency use registration when it is established beyond reasonable doubt there is a contravention conditions of approval.

(4) The EAC Guidelines on Emergency Registration for products for use in plantsor national guidelines for public health products.

15. **Registration of pest control Products for export and re-exports**

The Board may on payment of a prescribed fee determined by the Boardfrom time to time register pest control product for export or re-export only where satisfied that safety data sheet, certificate of analysis meets the requirement set by the Board.

16. **Sources of registered pest control products**

(1) Where a certificate of registration is issued under this regulation, the product shall be obtained from the declared source at the time of registration.

(2) An application for change of source/ additional source for the product shall be submitted to the Board as prescribed in **Form F** set out in the Second Schedule.

17. **Refusal to register pest control products**

(1) The Board may refuse to register a pest control product if in Board's opinion—

(a) the applicant for registration or the label for the pest control product does not comply with, the provisions of the Act and these Regulations;

(b) the information provided to the Board by the applicant is insufficient to enable the pest control product to be assessed or evaluated;

(c) the applicant fails to establish that the pest control product has merit or value for the purpose claimed when the pest control product is used in accordance with its label directions; or

(d) the use of the pest control product would lead to an unacceptable risk or harm to—

(i) things on or in relation to which the pest control product in intended to be used; or

(ii) public health, plants, animals or the environment.

18. **Suspension and revocation of certificates of registration**

(1) The Board may suspend or revoke a certificate of registration issued under these
Regulations for such time as the Board may determine.

(2) The powers conferred by paragraph (1) shall not be exercised by the Board except on one or more of the following grounds—

(a) that the matters stated in the application on which the certificate of registration was granted were false;

(b) that new scientific information has become available to the Board which renders pest control product unsafe or dangerous to use according to label instructions;

(c)A certificate of registration for a product not applied for renewal as per Regulations 11(2) and (3)

(d) that new information has become available to the Board indicating that the pest control product is sourced from a manufacturer, formulator or any facility other than that specified in the application forms and dossier for registration for the respective pest control product or sources authorized by the Board;

(e) that the principal or registrant withdraws the technical support to the local agent or distributor on the basis of which a pest control product was registered, in writing;

19. **Evaluation of Pest Control Products**

The Board shall consider and evaluate applications for registration in these regulations; and suspension or revocation of certificate of registration in regulation 17 and any other relevant consideration with the support of the Technical and Registration Committee of the Board.

20. **Notice to holder of certificate of registration**,

(1) Where the Board—

(a) refuses to register a pest control product; or

(b) intends to revoke the certificate of registration, it shall send to the applicant or the holder of a certificate of registration, as the case may be, a notice by registered post notifying him of the refusal or revocation and the reasons.

(2) the applicant may appeal to the Board within thirty days after which the suspension or revocation shall be effected.

21. **Appeals**

(1) An applicant or holder of a certificate of registration who has received a notice under Regulation 20 may within thirty days from the date which the notice is received by him appeal to the Cabinet Secretary responsible for matters agriculture.

22. **Records**

(1) A holder of a certificate of registration issued under these Regulations shall keep a record of all the quantities of pest control products stored, manufactured or sold by

him and the record shall—

(a) be maintained for five years from the time it is made; and

(b) be made available to the Board at such times and in much manner as the Board may require.

23. **Exemption from registration**

(1) A pest control product shall be exempt from registration if—

(a) it is for use by a person for research purposes if that use has been approved by the Board;

(b) it is a classical biological control agent for release by an authorized government agency

(c) it is a type or kind set out in the First Schedule and meets the conditions relevant to that substance as set out in that Schedule.

FIRST SCHEDULE

East African Community

One People, One Destiny

APPLICATION FORM FOR THE REGISTRATION OF A PEST CONTROL PRODUCT IN PARTNER STATES OF THE EAST AFRICAN COMMUNITY (EAC)

Form A1

Information for applicants

1. The applicant is the natural or legal person that manufactures the pest control product and/or places it on the market. After approval of the registration, the applicant will become the registration holder of the product.

2. The applicant shall be a legal entity in – *name of EAC country* –, or be represented by a local agent who is a permanent resident in – *name of EAC country* – and duly recognized by the national pesticide registration Board.

3. The application form shall be completed by a person duly authorized by the applicant.

4. The application shall be submitted in triplicate to:

– name and address of the national pesticide registration Board –

5. Every application must be accompanied by:
   a) proof of payment of the application fee as prescribed by the national pesticide registration Board;
   b) three (3) copies of the draft label
   c) three (3) copies of the technical dossier as per the data requirements detailed in List I (active ingredient) and List II (formulated product).

6. The applicant may be required to submit:
   a) Registration authorization letter: In case the applicant is not the owner of the TGAI/product, provide a letter in which the owner of the TGAI/product authorizes the applicant to apply for registration;
   b) sample of the pest control product, for bio efficacy trial purposes;
   c) a sample of the pest control product for residue trial purposes;

d) a sample of the technical grade of its active ingredient(s);

e) a sample of the analytical standard of its active ingredient(s);

f) any other sample as may be required by the pesticide registration Board

1	**PRODUCT**	
1.1	Product name (brand name)	
1.2	Type of formulation (CropLife code[1])	
1.3	Active ingredient(s) (common name)	
1.4	Active ingredient concentration(s)	
1.5	Patent status and expiry date (if applicable)	
1.6	Quick Response (QR) code (if available)	
2	**APPLICANT**	
2.1	Applicant name (corporate name of company)	
2.2	Status	☐ manufacturer ☐ formulator ☐other: ….
2.3	Business registration number	
2.4	Physical address	
2.5	Postal address	
2.6	Telephone number	
2.7	E-mail address	
2.8	Web site	
2.9	Contact person at applicant company	
2.10	Contact person telephone number	
3	**LOCAL AGENT**	
3.1	Local agent name (corporate name of company) (if different from applicant)	
3.2	Status	☐ formulator ☐ importer ☐ distributor ☐other: ….
3.3	Business registration number	
3.4	Physical address	
3.5	Postal address	

[1] The CropLife code is the two-letter code for the type of formulation according to the Crop Life International Catalogue of pesticide formulation types and international coding system. It can be found at: https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/2017/04/Technical-Monograph-2-7th-Edition-Revised-March-2017.pdf

3.6	Telephone number	
3.7	E-mail address	
3.8	Contact person at local agent	
3.9	Contact person telephone number	

4	**PURPOSE OF APPLICATION**			
a	☐ New pest control product containing a new active ingredient (a.i.)			
b	☐ New pest control product containing an a.i. already registered in the country			
c	☐ New source of active ingredient and/or formulation of an existing registration			
d	☐ Amendment or extension to an existing registration			
e	☐ Registration transfer (between registrants)			
f	☐ Other (specify):	…		
5	**INTENDED USE**			
5.1	Function/category of product (more functions/categories possible)	☐ Insecticide	☐ Fungicide	☐ Herbicide
		☐Acaricide	☐ Rodenticide	☐Molluscicide
		☐ Bactericide	☐ Defoliant	☐ Plant growth regulator
		☐ Other (specify):	…	
5.2	Type of use (more types possible)	☐ Agriculture	☐ Veterinary	☐ Public health
		☐ Household	☐ Forestry	☐ Industrial
		☐ Other (specify):	…	
5.3	Target pest(s)/disease(s) and crop(s)/use(s)	1	…	
		2	…	
		3	…	
6	**HAZARD CLASSIFICATION**			
6.1	WHO Hazard Class of the formulated product	☐ Class Ia	☐ Class Ib	☐ Class II
		☐ Class III	☐ Class U	
6.2	GHS classification of the formulated product (list all classifiable hazards)			
	Physical hazards	…		
	Health hazards	…		
	Environmental hazards	…		

7	**DECLARATION**	
	For and on behalf of ……. I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	…… Name in full (print)	…… Signature
	…… Official title	…… Date
	Official stamp of applicant/company	
8	**FOR OFFICIAL USE**	
	Application No: …	Remarks: ….
	Reception date: …	
	Fees received: ☐ Yes ☐ No	
	Amount paid:	
	Status of application:	☐ Approved ☐ Rejected ☐ Pending

Application Form for the Registration of a Biopesticide Product in Partner States of the East African Community (EAC)

East African Community

One People, One Destiny

Form A2

Information for applicants

7. The applicant is the natural or legal person that manufactures the pest control product and/or places it on the market. After approval of the registration, the applicant will become the registration holder of the product.

8. The applicant shall be a legal entity in – *name of EAC country* –, or be represented by a local agent who is a permanent resident in – *name of EAC country* – and duly recognized by the national pesticide registration Board.

9. The application form shall be completed by a person duly authorized by the applicant.

10. The application shall be submitted in triplicate to:

– Name and address of the national pesticide registration Board –

11. Every application must be accompanied by:

d) proof of payment of the application fee as prescribed by the national pesticide registration Board;

e) three (3) copies of the draft label

f) three (3) copies of the technical dossier as per the data requirements detailed in List I (active ingredient) and List II (formulated product).

12. The applicant may be required to submit:

g) Registration authorization letter: In case the applicant is not the owner of the TGAI/product, provide a letter in which the owner of the TGAI/product authorizes the applicant to apply for registration;

h) sample of the pest control product, for bio efficacy trial purposes;

i) a sample of the pest control product for residue trial purposes (where applicable);

j) a sample of the technical grade of its active ingredient(s)/ agent(s);

k) a sample of the analytical standard of its active ingredient(s) (Applicable for only Biochemicals);

l) any other sample as may be required by the pesticide registration Board

1	**PRODUCT**	
1.1	Product name (brand name)	
1.2	Type of formulation (CropLife code[2])	
1.3	Active ingredient(s)/Agent (s) (common name)	
1.4	Active ingredient/Agent (s) concentration(s)	
1.5	Patent status and expiry date (if applicable)	
1.6	Quick Response (QR) code (if available)	
2	**APPLICANT**	
2.1	Applicant name (corporate name of company)	
2.2	Status	☐ manufacturer ☐ formulator ☐other: ….
2.3	Business registration number	
2.4	Physical address	
2.5	Postal address	
2.6	Telephone number	
2.7	E-mail address	
2.8	Web site	
2.9	Contact person at applicant company	
2.10	Contact person telephone number	
3	**LOCAL AGENT**	
3.1	Local agent name (corporate name of company) (if different from applicant)	
3.2	Status	☐ formulator ☐ importer ☐ distributor ☐other: ….
3.3	Business registration number	
3.4	Physical address	
3.5	Postal address	
3.6	Telephone number	

3.7	E-mail address	
3.8	Contact person at local agent	
3.9	Contact person telephone number	

4	**PURPOSE OF APPLICATION**			
a	☐ New pest control product containing a new active ingredient (a.i.)/Agent			
b	☐ New pest control product containing an active ingredient/Agent already registered in the country			
c	☐ New source of active ingredient/Agent and/or formulation of an existing registration			
d	☐ Amendment or extension to an existing registration			
e	☐ Registration transfer (between registrants)			
f	☐ Other (specify):	…		
5	**INTENDED USE**			
5.1	Function/category of product (more functions/categories possible)	☐ Insecticide	☐ Fungicide	☐ Herbicide
		☐Acaricide	☐ Rodenticide	☐Molluscicide
		☐ Bactericide	☐ Defoliant	☐ Plant growth regulator
		☐Semio Chemical		
		☐ Other (specify):	…	
5.2	Type of use (more types possible)	☐ Agriculture	☐ Veterinary	☐ Public health
		☐ Household	☐ Forestry	☐ Industrial
		☐ Other (specify):	…	
5.3	Category of Biopesticide	☐ Microbial	☐Macrobial	
		☐ Botanicals	☐Semio chemicals	
5.4	Target pest(s)/disease(s) and crop(s)/use(s)	1	…	
		2	…	
		3	…	
		…		
6	**HAZARD CLASSIFICATION (FOR BIOCHEMICALS)**			
6.1	WHO Hazard Class of the formulated	☐ Class Ia	☐ Class Ib	☐ Class II

	product	☐ Class III	☐ Class U	
6.2	GHS classification of the formulated product (list all classifiable hazards)			
	Physical hazards	...		
	Health hazards	...		
	Environmental hazards	...		

	DECLARATION	
	For and on behalf of ……. I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	…… Name in full (print)	…… Signature
	…… Official title	…… Date
	Official stamp of applicant/company	
8	**FOR OFFICIAL USE**	
	Application No: …	Remarks: ….
	Reception date: …	
	Fees received: ☐ Yes ☐ No	
	Amount paid:	
	Status of application:	☐ Approved ☐ Rejected ☐ Pending

Complete the GAP Table for Efficacy Appendix xxx

GAP table for

		GAP rev. 1, date:
Product name **Kuvu 80WP** **Active ingredient(s)** **Mancozeb**		**Formulation type: WP** **Conc. of a.i:** **800g/Kg**
Applicant: **XYZ Agrochemicals**		

1	3	4	5	6	7		8	10		11	12	13	14
Us	**Crop and/**	**Fungi**	**Pests or**	**Application**				**Application rate**				**PHI**	**Rema**

e-No.	**or situation** (crop destination / purpose of crop/growth habitat e.g indoor or outdoor)	**cide/ Herbicide/Insecticide/ Others (specify)**	**Group of pests controlled** (additionally: developmental stages of the pest or pest Group, where necessary [e.g. larvae, adults])	Method / Kind	Timing / Growth stage of crop & season	Max. number of applications per crop or season	Min. interval between applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g/kg a.i/ha a) max. rate per appl. b) max. total rate per crop or season	g/kg of a.i. per hL min. -- max.	Water L/ha min / max	(days)	**rks:**
1	Indicator crop: (e.g.Tomato)	e.g. Fungicide	*Indicator pest(s): e.g. Phytophthora infestans*(late blight)	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	160 – 200g	600 – 1000 L	14 days	
2	To be extrapolated to: Potato	F	*Phytophthora infestans*(late blight	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	160 – 200g	600 – 1000 L	14 days	

1	3	4	5	6	7		8	10		11	12	13	14
Use-No.	**Crop and/ or situation** (crop destination / purpose of crop/growth habitat e.g indoor or outdoor)	**Fungicide/ Herbicide/Insecticide/ Others (specify)**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest Group, where necessary [e.g. larvae, adults])	**Application**				**Application rate**				**PHI** (days)	**Remarks:**
				Method / Kind	Timing / Growth stage of crop & season	Max. number of applications per crop or season	Min. interval between applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g/kg a.i/ha a) max. rate per appl. b) max. total rate per crop or season	g/kg of a.i. per hL min. -- max.	Water L/ha min / max		

FORM A3

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT (GENERIC)

Introduction

These guidelines are for registration of identical products that are manufactured after the expiry of the patent of an original/proprietary registered product. These identical products are generally referred to as generics and will include conventional and biochemical pesticides. A pre-registration consultation between the applicant and the registration Board is strongly recommended.

TRADE NAME:……

Information for Applicants

1. The application form must be completed by a duly authorized person.

2. The application must be submitted in triplicate to:

The Managing Director/Secretary

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address: info@pcpb.go.ke.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

Website:

https://www.pcpb.go.ke/

3. Every application must be accompanied by:-

a) application fee as prescribed (Registration fee is payable upon approval by the Board).

b) 3 copies of the draft label as per PCPB requirements.

4. The applicant may 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 the Board.

5. List I and II are supplied as a check list and an index to ensure that the applicant has provided the relevant data.

6. The application must be accompanied by a technical dossier as per PCPB data requirements (Lists I and II).

7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

PURPOSE OF APPLICATION (tick/fill as appropriate)

a. Pest control product containing a generic active ingredient ☐ i) Date of expiry of patent…….. ii) Name of former patent holder……..
b. Pest control product 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.ginerts, source of technical material e.t.c) ☐
e. Other (Explain) …… …… ……

f. Will the product be marketed under own label? Yes ☐ No ☐ If no specify……..
Proposed date of marketing……

1. APPLICANT	
1.1 Identification	
Name of applicant/Corporate name of company	
Business Registration No.:	
Name of registration holder	
1.2 Status: (manufacturer / formulator/ other)	

1.3 Physical Address	
1.4 Postal Address:	
1.5 Telephone: (and area code)	
1.6 Fax: (and area code)	
1.7 e-Mail:	

2. Name of local agent in country: (if different from registration holder)	
Business Registration No.:	
2.1 Status: (Importer/formulator/distributor)	
2.2 Physical Address	
2.3 Postal Address:	
2.4 Telephone: (and area code)	
2.5 Fax: (and area code)	
2.6 e-mail:	

<table>
<tr><td>3 PRODUCT</td><td></td></tr>
<tr><td rowspan="3">3.1 Designation
(Description
of product)</td><td>Trade name:</td></tr>
<tr><td>Trade mark:</td></tr>
<tr><td>Trade mark holder:</td></tr>
<tr><td>3.2 Function of product: (eg.
Insecticide, herbicide etc.)</td><td></td></tr>
<tr><td>3.3 Intended use: (Public health, industrial, agriculture, forestry, etc.</td><td></td></tr>
<tr><td>3.4 Application for
(a) Single crop/pest combination
(b) Multiple uses (using the extrapolation tool)
(c) If YES under (b) above, refer to the crop grouping and data extrapolation guidelines to identify the relevant indicator pest and crop for efficacy.</td><td>Yes ☐ NO ☐

Yes ☐ No ☐</td></tr>
<tr><td>3.5 Indicator pest(s)

3.6 Indicator host crop (s)</td><td><table><tr><td>Indicator pest (Common and scientific name)</td><td>Indicator crop (Common and scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.7 Requested extrapolation pests and crops</td><td><table><tr><td>Pest (Common and scientific name)</td><td>Crop (Common and scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.8 Method, dosage rates and frequency of application:</td><td>Complete the GAP Table for Efficacy Appendix xxx</td></tr>
</table>

3.9 Type of formulation: (eg. EC, WP, etc.)		CropLife International(CLI*) Code (if available)	
3.10 a) Is the product registered in country of manufacture?	Yes ☐ No ☐ If no, give reasons……		
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ If no, give reasons ……..		
3.11 Proof of registration in SEARCH** country/ies: (names)			
3.12 Proof of registration in other countries.			
3.13 Customs Tariff Code: (Brussels Tarrif Nomenclature)			

4 **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 %

*Formerly Global Crop Protection Federation (GCPF)

**SEARCH - Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration

5. FORMULATION			
5.1 Formulator: (Name) Postal Address: Physical address:			
5.2 Internal code:			
5.3 Composition (Information on composition may be attached in sealed envelope)			
Ingredients and Function:	g/L	g/Kg	Range

6. TOXICOLOGY (formulated product)			
6.1 Rat:	Acute Oral (LD_{50} mg/Kg)	Acute Dermal (LD_{50} mg/Kg)	Inhalation LC_{50} (mg/L/4 hour)
	Experimental	Experimental	Experimental

6.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
6.3 Skin Sensitization in		None ☐ Mild ☐ Moderate ☐ Severe ☐	
6.4 WHO	Ia	Ib	II	III	Table V
6.5 Summary of other mammalian toxicological studies: eg. Livestock, wildlife, poultry, pets					

7 Summary of environmental effects	
7.1 Toxicity to bees:	
7.2 Toxicity to fish and other aquatic organisms:	
7.3 Toxicity to birds:	
7.4 Toxicity to earthworms and soil micro-organisms:	
7.5 Toxicity to other non-target organisms:	
7.6 Persistence in environment:	
7.7 Other effects: Specify	

8. PACKAGING	
8.1 Packaging material / container:	
8.2 Pack size(s):	
8.3 Disposal of empty container(s):	

9. OTHER SPECIFIC REQUIREMENTS
9.1 Operator exposure
9.1.1 Dermal absorption.
9.1.2 Likely operator exposure under field conditions
9.2 Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).

10. 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 is recognized by all SEARCH countries.

FORM A3,
LIST I

ACTIVE INGREDIENT: DOSSIER INDEX

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, results of toxicological and ecotoxicological studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i)	**Annex No. in dossier if study included**	**Official use only**
1. **DESIGNATION/IDENTITY OF a.i.**		
1.1 Common name (ISO)		
1.2 Manufacturer or Development code		
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.4 Methods of manufacture (synthesis Pathways) to include relevant impurities i.e. manufacturing impurities, water content &insolubles may be sent direct to PCPB.		
1.5 Specifications of purity supported by random ”5” batch analysis from GLP certified laboratory.		
1.6 Active ingredient content supported by random “5” batch analysis from GLP certified laboratory.		
1.7 Chemical name (IUPAC)		
1.8 Chemical group		
1.9 Structural formula		
1.10 Empirical formula		

1.11 Molecular mass		
1.12 CAS Number		
1.13 Expiry of patent		

2. PHYSICAL AND CHEMICAL PROPERTIES

The applicant must provide original information specific to the generic product (technical grade)

2.1 Physical state		
2.2 Colour		
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 DT_{50} ….. Days ……. ^{0}C ……. pH		
2.8 Photolysis		
2.9 Solubility in water ……..^{0}C …….. pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point ^{0}C		
2.13 Melting point ^{0}C		
2.14 Decomposition temperature ^{0}C		
2.15 Method of Analysis and Impurities		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products		
2.17 Stability in organic solvents used in formulation		
2.18 Stability in air; effect of light, identity of breakdown Products		
2.19 Thermal stabilty, identity of breakdown		

products.		
2.20 Flammability		
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		
2.26 Technical Equivalence (if applicable)[3]		

3.TOXICOLOGY

Where technical equivalence is proven, provide studies from 3.1 to 3.3 specific to the technical grade material. Information required from 3.4 to 6.4 may be sourced from published literature.

Where technical equivalence is not proven then all the studies specific to the technical grade material from 3.1 to 6.4 must be provided.

Where an impurity is present at a concentration greater than 1g/Kg or is known or suspected to be of toxicological significance then its toxicological profile must be submitted.

3.1 ADI		
3.2 Acute oral LD_{50} mg/Kg rat/rabbit		
3.3 Acute dermal LD_{50} mg/Kg (rat)		
3.4 Inhalation LC_{50} mg/L hour (rat)		
3.5 Skin irritation (rabbit)		
3.6 Eye irritation (rabbit)		
3.7 Skin sensitization (guinea pig)		
3.8 Reproduction (specify species)		
3.9 Subchronic toxicity 90 day NOEL mg/Kg/day		

[3]Technical equivalence – refer to dossier index

3.10 Chronic toxicity NOEL mg./Kg/day		
3.11 Carcinogenicity (life time) NOEL mg/Kg/day		
3.12 Neurotoxicity NOEL mg/Kg/day		
3.13 Teratogenicity NOEL mg/Kg/day		
3.14 Mutagenicity /Genotoxicity		
3.15 Metabolism (rat)		
3.16 Other studies		

4. ACTIVE INGREDIENT

ECO-TOXICOLOGY (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		
Reproduction		
BCF		
LD_{50} mg/Kg		
NOEL		
Reproduction		
BCF		
4.3 Daphnia		

LC_{50} mg/L		
NOEL		
4.4 Algae		
EC_{50} mg/L (96 hours)		
4.5 Bees		
LD_{50}		
µg/bee		
4.6 Earthworms		
LC_{50} mg/Kg		
4.7 Soil micro-organisms		

5. BEHAVIOUR IN ENVIRONMENT

5.1 Behaviour, ways of degradation, degradation products in soil:		
5.1.1 Major metabolites		
5.1.2 DT_{50} (days)		
5.1.3 Mobility of a.i.		
5.1.4 Adsorption / desorption		
5.1.5 Mobility of metabolites		
5.2 Behaviour, ways of degradation, degradation products in water		
5.2.1 Major Metabolites		
5.2.2 DT_{50} (days)		
5.2.3 Surface water		
5.2.4 Ground water		
5.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		

6. RESIDUES		
6.1 Major metabolites		
6.2 Metabolism		

6.3 Behaviour of residues		
6.4 MRL codex or other certified sources		
6.5 Method of residue analysis		

7. MODE OF ACTION		
8. OTHER SPECIFIC REQUIREMENTS		
8.1 Residue data from a GLP certified laboratory.		
8.2 Proposed pre-harvest intervals, withholding Periods in case of post-harvest use.		
8.3 Effect 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.		

FORM A3,LIST II

FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use Collaborative International Pesticides Analytical Council (CIPAC) methods for Physical/Chemical properties.

Summaries of the methods used and the results of toxicological and ecotoxicological studies, methods of analysis etc. should be given.

Numbering used in the dossier must correspond with that used in Form A4.

FORMULATED PRODUCT		
1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier if study included**	**Official use only**
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source, MSDS and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		
1.9 Density		
1.10 Bulk density		
1.11 Flammability		

1.12 Flash point		
1.13 Explosivity		
1.14 In-compatibility with other pest control Products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		
1.20 Wettability		
1.21 Solubility in water		
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Wet sieve test		
1.29 Dry sieve test		
1.30 Methods of Analysis		
1.31 Detailed composition supported by analytical evidence from GLP certified laboratory		
1.32 Other properties (where applicable)		

2. TOXICOLOGY		
2.1 Rat Acute oral LD_{50} mg/Kg		

2.2 Acute dermal LD_{50} mg/Kg		
2.3 Inhalation LC_{50} mg/L / 4hours		
2.4 Rabbit Skin irritation		
2.5 Eye irritation		
2.6 Skin Sensitization in guinea pig or Local lymph node assay (LLNA)		
2.7 WHO classification		
2.8 Other studies		

Detailed studies in 2.1 to 2.6 MUST be original and specific to the formulation. The studies should be conducted in GLP certified laboratories.

	Annex No. in dossier if study included	**Official use only**
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
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		
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. BIOEFFICACY/USES (New label claims with this application)		
	Annex No. in dossier if study included	**Official use only**
5.1 Crop/public health etc		
5.2 Target organism		
5.3 Rate		
5.4 Stage of treatment		
5.5 Directions for use		
5.6 Residue data and pre-harvest interval Refer to section 6 in the guidelines		
5.7 Provide Efficacy data from similar climatic zones		
5.8 Phytotoxicity/Crop safety Refer to section 5.7 in the guideline		
5.9 Contraindications		

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

7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medical surveillance, on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry etc.		
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.		

FORM A4

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT (SPRAY ADJUVANT)

A Spray adjuvant: Is a compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a pest control product to which it is added.

TRADE NAME:……..

Information for Applicants

1. The application form must be completed by a duly authorized person.
2. The application must be submitted in triplicate to:

The Managing Director/Secretary

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

Website:

https://www.pcpb.go.ke/

3. Every application must be accompanied by:-

a) application fee as prescribed (Registration fee is payable upon approval by the Board).

b) 3 copies of the draft label as per PCPB requirements.

4. The applicant may be required to submit:-

e) a sample of the pest control product;
f) a sample of the laboratory standard of its active ingredient;
g) any other sample as may be required by the Board.

5. List I is supplied as a check list and an index to ensure that the applicant has provided the relevant data.

6. The application must be accompanied by a technical dossier as per PCPB data requirements (dossier index).

7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

PURPOSE OF APPLICATION (tick as appropriate)

a. A pest control product which is an adjuvant	☐
b. Pest control product 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) …… …… ……

f. Will the product be marketed under own label? Yes ☐ No ☐ If no specify……
Proposed date of marketing……

1. APPLICANT	
1.1 Identification	
Name of applicant/Corporate name of company	
Business Registration No.:	
Name of registration holder	
1.8 Status: (manufacturer / formulator/ other)	
1.9 Physical Address	

1.10 Postal Address:	
1.11 Telephone: (and area code)	
1.12 Fax: (and area code)	
1.13 E-Mail:	

2. Name of local agent in country: (if different from registration holder)	
Business Registration No.:	
3.1 Status: (Importer/formulator/distributor)	
3.2 Physical Address	
3.3 Postal Address:	
3.4 Telephone: (and area code)	
3.5 Fax: (and area code)	
3.6 e-mail:	

3. PRODUCT	
3.1 Designation (Description of product)	Trade name:
	Trade mark:
	Trade mark holder:
3.2. Spray adjuvant function: (wetter, surfactant, etc)	
3.3 Intended use: (Public health, industrial, agriculture, forestry, etc.	
3.4 Application for (d) Single crop/pest combination (e) Multiple uses (using the extrapolation tool) (f) If YES under (b) above, refer to the crop grouping and data extrapolation guidelines to identify the relevant indicator pest and crop for efficacy.	Yes _____ NO Yes ☐ No ☐

3.5 Target use e.g product and crop/animal 3.6 Indicator pest (s) 3.7 Indicator host crop (s)	Indicator pest (Common and scientific name)	Indicator crop (Common and scientific name)

3.8 Requested extrapolation pests and crops	Pest (Common and scientific name)	Crop (Common and scientific name)

3.9 Method, dosage rates and frequency of application:	Complete the GAP Table for Efficacy Appendix xxx

3.10 Type of formulation: (e.g. EC, WP, etc.)		CropLife International (CLI*) Code (if available)	
3.11a) Is the product registered in country of manufacture?	Yes ☐ No ☐ If no, give reasons		
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ If no, give reasons		
3.12 Registration in SEARCH** country/ies: (names)			
3.13 Proof of existing registration in other country(ies)			
3.14 Customs Tariff Code: (Brussels Tarrif Nomenclature)			

4. SPRAY ADJUVANT FORMULA (attach confidential formula)

*CLI – CropLife International formerly Global Crop Protection Federation (GCPF)

**SEARCH - Southern and Eastern African Regulatory Committee on Harmonisation of Pesticide Registration

Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Spray adjuvant function	Percentage

5. FORMULATION			
5.1 Formulator: (Name) Postal Address: Physical address:			
5.2 Internal code:			
5.3 Composition (Information on composition formula may be attached in sealed envelope)			
Ingredients	g/L	g/Kg	Range

6. TOXICOLOGY (formulated product)			
6.1 Rat:	Acute Oral (LD_{50} mg/Kg)	Acute Dermal (LD_{50} mg/Kg)	Inhalation LC_{50} (mg/L/4 hour)
	Experimental /calculated	Experimental /calculated	Experimental/ 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	Table V
6.5 Summary of other mammalian toxicological studies: eg. Livestock, wildlife, poultry, pets					

7. Summary of environmental effects (where applicable e.g. sensitive areas)	
7.1 Toxicity to bees:	
7.2 Toxicity to fish and other aquatic organisms:	
7.3 Toxicity to birds:	
7.4 Toxicity to earthworms and soil micro-organisms:	
7.5 Toxicity to other non-target organisms:	
7.6 Persistence in environment:	
7.7 Other effects: Specify	

8 PACKAGING	
8.1 Packaging material / container:	
8.2 Pack size(s):	
8.3 Disposal of empty container(s):	

9. OTHER SPECIFIC REQUIREMENTS
9.1 Operator exposure
9.1.1 Dermal absorption.
9.1.2 Likely operator exposure under field conditions
9.2 Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).

10. 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
	FOR OFFICIAL USE Remarks ……..

Official Stamp of Applicant / Company	…… …… …….. …… Signed: Date:

FORMULATED PRODUCT/ SPRAY ADJUVANT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use Collaborative International Pesticides Analytical Council Limited (CIPAC) methods for Physical/Chemical properties.
Summaries of the methods used and the results of toxicological and methods of analysis etc. should be given. Numbering used in the dossier must correspond with that used in Form A4.

FORMULATED PRODUCT/Spray adjuvant		
1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier if study included**	**Official use only**
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source, MSDS and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the		

formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		
1.9 Density		
1.10 Bulk density		
1.11 Flammability		
1.12 Flash point		
1.13 Explosivity		
1.14 Incompatibility with other pest control products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		
1.20 Wettability		
1.21 Solubility in water		
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Surface tension (where applicable)		
1.29 Adhesion		
1.30 Methods of Analysis		
1.31 Detailed composition supported by analytical evidence from certified		

laboratory		
1.32 Other properties (where applicable e.g penetration)		

2. TOXICOLOGY	**Annex No. in dossier if study included**	**Official use only**
2.1 Acute oral LD_{50} mg/Kg (Rat)		
2.2 Acute dermal LD_{50} mg/Kg		
2.3 Inhalation LC_{50} mg/L / 4hours		
2.4 Skin irritation (Rabbit)		
2.5 Eye irritation		
2.6 Skin Sensitization in guinea pig or Local lymph node assay (LLNA)		
2.7 WHO classification		
2.8 Other studies		

Detailed studies in 2.1 to 2.6 MUST be original and specific to the formulation. The studies should be conducted in GLP certified laboratories.

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		
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. BIOEFFICACY/USES		
SPRAY ADJUVANT	**Annex No. in dossier if study included**	**Official use only**
5.1 Product and Crop/public health etc		
5.2 Spray adjuvant function		
5.3 Adjuvant Rates		
5.4 Spray carrier		
5.5 Stage of treatment		
5.6 Directions for use		
5.7 Residue data and pre-harvest interval Refer to section 8 in the guidelines		
5.8 Provide Efficacy data from similar climatic zones		
5.9 Phytotoxicity/ Crop safety Refer to section 5.7 in the guideline		

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

7. BEHAVIOUR IN ENVIRONMENT

Where used in environmentally sensitive areas e.g aquatic systems, information on environmental impact potential should be submitted.

7.1 Behaviour, ways of degradation, degradation products in soil:		
7.1.1 Major metabolites		
7.1.2 DT_{50} (days)		
7.1.3 Mobility of a.i.		
7.1.4 Adsorption / desorption		
7.1.5 Mobility of metabolites		
7.2 Behaviour, ways of degradation, degradation products in water		
7.2.1 Major Metabolites		
7.2.2 DT_{50} (days)		
7.2.3 Surface water		
7.2.4 Ground water		
7.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		

8. RESIDUES (where applicable in food crops/animals)		
8.1 Major metabolites		
8.2 Metabolism		
8.3 Behaviour of residues		
8.4 MRL codex or other certified sources		
8.5 Method of residue analysis		
8.6 Residue data from a GLP certified laboratory.		
8.7 Proposed pre-harvest intervals / withholding periods in case of post-harvest use.		
8.8 Effect on taint, odour, taste, or other quality aspects due to residues in or on fresh or processed products.		
8.9 Effects on industrial processing		

and/or household preparation on the nature and magnitude of residues.		
8.10 Residue data in succeeding or rotational crops where presence of residues might be expected.		

9 MODE OF ACTION		

FORM A5

APPLICATION FOR REGISTRATION AS A LOCAL AGENT

Information for Applicants

1. "Agent" means a person or company who has/that has been appointed to act on behalf of a registrant in accordance with regulation 4(2) of the Pest Control Products (Registration) Regulations.
2. The application form must be completed by a duly authorized person.
3. The application must be submitted to:

The Managing Director/Secretary

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

Website:

https://www.pcpb.go.ke/

4. Every application must be accompanied by:-

   a) An original letter from the registrant,
   b) A binding agreement entered between the registrant and the agent,

Product Details

Trade name……

Name of Manufacturer……

Name of Formulator……

Name of Registrant……

Name of agent……

Period for which agent has been appointed……

Signature of applicant (local agent) ……Date……..……

Signature of Registrant ……Date……..

Official Stamps of Applicant and Registrant

FORM A6

APPLICATION FOR CHANGE OF AGENCY.

Information for Applicants

2. "Agent" means a person or company who has/that has been appointed to act on behalf of a registrant in accordance with regulation 4(2) of the Pest Control Products (Registration) Regulations.
3. The application form must be completed by a duly authorized person.
4. The application must be submitted to:

The Managing Director/Secretary

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

Website:

https://www.pcpb.go.ke/

5. Every application must be accompanied by:-
   c) An original letter from the registrant,
   d) A binding agreement entered between the registrant and the agent,
   e) An original letter of no objection from the former agent,
   f) Application fee of Ksh 20,000 per product (change of agency fee is payable upon approval by PCPB after meeting the other requirements),
   g) A copy of the draft label as per PCPB requirements,
   h) Proof of licensing of the new agent by PCPB.

Product Details

Trade name……

Registration Number(If registered)……Status of registration……..

Name of Manufacturer……..……..

Name of formulator……..

Period of which agent has been appointed……..

Name of Registrant……..

Signature ……..Date……..

Official Stamp

Name of former agent……

Signature ……..Date……...

Official Stamp.

Name of new agent……

Signature ……..Date……..

Official Stamp

For official use only

Please check whether the following documents have been provided:

Registration Department:

1. Has an original letter from the registrant been vided? Yes

   No

2. Has an original letter of no objection from the former agent been provided?

   Yes No

3. Has the applicant attached a copy of the draft label?

   Yes ☐ No ☐

Inspection Department:

4. Is the applicant licensed as a pesticide dealer/agent with PCPB in the current year? ☐ .....Yes……☐ ...No…… If yes indicate licence No.

Accounts:

5. Has the applicant paid the change of agency fee? ☐ ☐

   …….Yes……..No……

   Indicate Receipt Number…….. Date……..

   ☐ ☐

6. Has the applicant paid the dealers/agency license fee?

   ……Yes……No……

   Indicate Receipt Number…….. Date……..

Recommended ☐	Not Recommended ☐	Recommended ☐	Not Recommended ☐	Recommended ☐	Not Recommended ☐
Date……. …….. Registration Officer		Date……. …….. Inspector		Date……. …….. Accountant	

……..

Approved by Managing Director

Pest Control Products Board ***Date ……..***

Changes effected by (IT Officer)……Date……

Form A7.

CONFIDENTIAL BUSINESS INFORMATION SUBMISSION/RECEIPT FORM

		Provided		**Remarks**
		Yes	**No**	
1	Method of manufacture (e.g. synthesis pathway)			
2	Specifications of the technical grade (active ingredient)			
3	Composition of the formulation			
4	Method of analysis for impurities			
5	'5-batch' analysis; including chromatographs			
6	Any other information			

Date received	
Trade name of the Product	
Active ingredient(s)	
Registrant	
Manufacturer(s) of active ingredient	
Formulator	
Exporter	
Local agent	
Submitted by (**Full Name andsignature)***	
Received by: **Officer's name andsignature**	

Handed over to the **Head of department.** **Signature:**	

**** Confidential business information received as it is subject to technical evaluation.***

Form A8

CONFIDENTIALITY DECLARATION

I……from ……..(*company oflocal agent, representative*) declare that I shall maintain confidentiality of all Confidential Business information (CBI) as provided for under the Pest Control Products Act and Regulations made thereunder.

Signature……..

Name of agent/representative

Designation

Date……..

FORM A9

THE PEST CONTROL PRODUCTS (MISCELLANEOUS FORMS)

SUBMISSION OF SAMPLE (S) FOR EFFICACY TESTING.

This form should be filled in duplicate: Part I and II to be filled by the Applicant

I) Product Details

Trade name……

Formulation type……

Active ingredient (s) ……

Concentration of active ingredient(s)……..

Quantity of sample (Liters or grams)……..

Number of packages……..

REF: (Permit No. and date)……

Name of Applicant (Local agent)……..

FORM A9

II) <u>Submission details</u>

Submitted by:

Name……Signature……Date……...

III) <u>Delivery details</u>

Received on behalf of PCPB by:

Name……Signature……Date……...

Institution(s) of destination……..

Means of delivery:

A. PCPB personnel

Name of Person delivering……

Date of delivery……...

Received by……..

Signature……

Official stamp……..

B. Courier Service

Name of company……..

Contact person……..……

Charges (Attach receipt)……..

Date of delivery……

Official stamp……

Receiving Institution ……..

Date of receipt……..……...

Person receiving……..

Signature……..

Official Stamp……

FORM A10

THE PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2022.

APPLICATION FOR CHANGE OF TRADE NAME FOR A PEST CONTROL PRODUCT.

Information for Applicants

6. The application form must be completed by a duly authorized person/Agent
7. The application must be submitted to:
   The Managing Director, Pest Control Products Board (PCPB) P.O. Box 13794, 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 - 4446115/4450242 Fax: 254- 020- 4449072.

8. Every application must be accompanied by:-
   i) An original consent letter from the manufacturer/principal
   j) A copy of the draft label as per PCPB requirements,
   k) Proof of licensing as a dealer with Pest Control Products by PCPB
9. The applicant shall be required to submit a sample of the pest control product;
10. The applicant may be required to submit:
    h) A sample of the technical grade of its active ingredient;
    i) A sample of the laboratory standard of its active ingredient;
    j) Any other information as may be required by the Board.

6. Evidence from Kenya Intellectual Property Institute (KIPI) that the new trade name is available for use.

Product Details

Current Trade Name……

Proposed Trade Name……

Reason for change……..

Stage of registration

i) Registered (indicate registration No.)……

(Trade name to be in use 6 months after approval to allow exhaustion of old stock)

ii) Undergoing trials (State institution carrying out trials and permit No.)
iii) Other (indicate**)**

Name of Manufacturer……..……..

Name of Registrant (Proprietary owner of Technical information)
……..

Name of agent…….…..…

Signature of applicant ……..Date…….

Official Stamp of Applicant / Company

For official use only

Please check whether the following documents have been provided:

Registration Department:

7. Has an original letter from the registrant been ☐vided? ☐Yes ☐ No
8. Has the applicant attached a copy of the draft label?
   ☐ Yes ☐ No
9. Has KIPI confirmed availability of new trade name? Yes--- No----
10. Has the applicant submitted a sample of the pest control product? Yes--- No----
    -

FORM A10

Inspection Department:

11. Is the applicant licensed as a pesticide dealer/agent with PCPB in the current year? ☐ .....Yes☐……..No…… If yes indicate licence No.

Accounts:

12. Has the applicant paid the dealers/agency lic☐e fee? ☐

……Yes……No……

Indicate Receipt Number…….. Date……..

13. Departmental recommendations

Recommended ☐	Not Recommended ☐	Recommended ☐	Not Recommended ☐	Recommended ☐	Not Recommended ☐
Date……. …….. Registration Officer		Date……. …….. Inspector		Date……. …….. Accountant	

14. Recommendation of the Technical and Registration Committee of the Board

Recommended ☐ Not Recommended ☐ Date……..

15. Decision by the Board of Management

Approved ☐ Not Approved ☐ Date……

16. Changes effected on List of Products and data base by (IT Officer)

Signature……

Date……

FORM A11

REPUBLIC OF KENYA

PEST CONTROL PRODUCTS ACT, CAP 346, 1982.

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT FOR USE IN PAINT FOR IN-CAN AND FILM PRESERVATIVES

Information for Applicants

1. The application form must be completed by a duly authorized person.

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

info@pcpb.go.ke/md@pcpb.go.ke

Tel.254-2-8021846/7/8,

Fax 254-2-8021865

3. Every application must be accompanied by:-

a) Application fee as prescribed (Registration fee is payable upon approval by the Board).

b) 3 copies of the draft label as per PCPB requirements.

4. The applicant may be required to submit:-

k) a sample of the pest control product;
l) a sample of the technical grade of its active ingredient;
m) a sample of the laboratory standard of its active ingredient;
n) any other sample as may be required by the Board.

5. List I and II are supplied as a check list and an index to ensure that the applicant has

provided the relevant data.

6. The application must be accompanied by a technical dossier as per PCPB data

requirements (Lists I and II attached).

7. An applicant who is not a resident in Kenya must appoint an agent permanently resident

in Kenya and duly recognized by the Pest Control Products Board.

TRADE NAME……

PURPOSE OF APPLICATION (tick as appropriate)

a. Pest control product containing a new active ingredient	☐
b. Pest control product 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……..
Proposed date of marketing……

1. APPLICANT	
1.1 Identification	
Name of applicant / Corporate name of company	
Business Reg No.:	
Name of registration holder	
Name of local agent in country: (if different from registration holder)	
1.14 Status: (Importer/formulator/distributor)	
Business Registration No.:	
1.15 Physical Address	
1.16 Postal Address:	
1.17 Telephone: (and area code)	
1.18 Fax: (and area code)	

1.19 e-Mail:			
2. PRODUCT			
2.1 Designation (Description of product)	Trade name:		
	Trade mark:		
	Trade mark holder:		
2.2. Function of product: (eg. Insecticide, herbicide etc.)			
2.3 Intended use: (Public health, industrial, agriculture, forestry, etc.			
2.4 Target pest(s) and host(s)			
2.5 Method, dosage rates and frequency of application:			
2.6 Type of formulation: (eg. EC, WP, etc.)		Crop Life International(CLI*) Code (if available)	
2.7 a) Is the product registered in country of manufacture?	Yes ☐ No ☐ If Yes, attach a copy of certificate, If no, give reasons		
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ If Yes, attach a copy of certificate, If no, give reasons		

2.8 Registration in SEARCH* country/ies: (names)	
2.9 Existing registration No(s) and country(s).	
2.10 Customs Tariff Code: (Brussels Tarrif Nomenclature)	

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. FORMULATION

4.1 Formulator: (Name)

Postal Address:

Physical address:

4.2 Internal code:

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

Ingredients and Function:	g/*l*	g/kg	Range

* Formerly GCPF

* SEARCH - Southern and Eastern African Regulation Committee on Harmonisation of

Pesticide Registration

5. TOXICOLOGY (formulated product)			
5.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} mg/kg)	Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
5.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
5.3 Skin Sensitization in guinea pig: (tick)	None ☐	Mild ☐	Moderate ☐ Severe ☐

5.4 WHO classiffication:	Ia	Ib	II	III

5.5. Summary of other toxicological studies: eg. wildlife, poultry, pets

5.6 Summary of environmental effects	
5.6.1 Toxicity to bees:	
5.6.2 Toxicity to fish and other aquatic organisms:	
5.6.3 Toxicity to birds:	
5.6.4 Toxicity to earthworms and soil micro-organisms:	
5.6.5 Toxicity to other non-target organisms:	
5.6.6 Persistence in environment:	
5.6.7 Other effects: Specify	
6. PACKAGING	
6.1 Packaging material / container:	
6.2 Pack size(s):	
6.3 Disposal of empty container(s):	
7. OTHER SPECIFIC REQUIREMENTS	
7.1 Operator exposure	
a). Dermal absorption.	
b). Likely operator exposure under field conditions	
c). Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).	

<table>
<tr><td colspan="2">8. DECLARATION</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>……..
Name in full (printed)</td><td>……..
Signature</td></tr>
<tr><td>……
Official Title</td><td>……
Date</td></tr>
<tr><td>Official Stamp
of Applicant / Company</td><td>FOR OFFICIAL USE

Remarks ……..
……
……..

…….. ……
Signed: Date:</td></tr>
</table>

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

FORM A11, LIST I

ACTIVE INGREDIENT: DOSSIER INDEX

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, results of toxicological and ecotoxicological studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more that one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT(a.i)	**Annex No. in dossier if study included**	**Official use only**
1. **DESIGNATION/IDENTITY OF a.i.**		
1.1 Common name (ISO)		
1.2 Manufacturer or Development code		
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.7 Methods of manufacture(synthesis pathways), may be sent direct to PCPB.		
1.5 Chemical name (IUPAC)		
1.6 Chemical group		
1.7 Structural formula		
1.8 Empirical formula		
1.9 Patent status		

Is the a.i. under patent?		
Who is patent holder		
Expiry date		
1.10 Molecular mass		
1.10CAS Number		

2. PHYSICAL AND CHEMICAL PROPERTIES

2.1 Physical state		
2.2 Colour		
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 DT_{50} ….. Days …… ^{0}C …… pH		
2.8 Photolysis		
2.9 Solubility in water ……^{0}C ……. pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point ^{0}C		
2.13 Melting point ^{0}C		
2.14 Decomposition temperature ^{0}C		
2.15 Method of Analysis and Impurities		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products		
2.17 Stability in organic solvents used in formulation		

2.18 Stability in air; effect of light, identity of breakdown Products		
2.19 Thermal stabilty, identity of breakdown product.		
2.20 Flammability		
2.21 Flash point		
2.22 Explosive properties		
2.23 Oxidizing properties		
ACTIVE INGREDIENT	**Annex No. in dossier if study included**	**Official use only**
2.24 Absorption spectra – UV/Visible, infra-red, NMR MS		
2.25 Reactivity towards container material		

3. TOXICOLOGY

3.1 Acute oral LD_{50} mg/kg rat/rabbit		
3.2 Acute dermal LD_{50} mg/kg (rat)		
3.3 Inhalation LC_{50} mg/l hour (rat)		
3.4 Skin irritation (rabbit)		
3.5 Eye irritation (rabbit)		
3.6 Skin sensitisation (guinea pig)		
3.7 Reproduction (specify species)		
3.8 Subchronic toxicity 90 day NOEL mg/kg/day		
3.9 Chronic toxicity NOEL mg./kg/day		
3.10 Carcinogenicity (life time) NOEL		

mg/kg/day		
3.11 Neurotoxicity NOEL mg/kg/day		
3.12 Teratogenicity NOEL mg/kg/day		
3.13 Mutagenicity /Genotoxicity		
3.14 Metabolism (rat)		
3.15 Other studies		

Notes

For long term studies individual studies or published literature may be acceptable.

4. ACTIVE INGREDIENT

ECO-TOXICOLOGY (Active ingredient – technical grade	**Annex No. in dossier if study included**	**Official use only**
4.1 Birds (2 species)	LD_{50} mg/kg	
	NOEL	
	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-organisms		

5. BEHAVIOUR IN ENVIRONMENT

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		
	Annex No. in dossier if study included.	**For official use only.**
5.2 Behaviour, ways of degradation, degradation products in water		
5.21 Major Metabolites		
5.22 DT_{50} (days)		
5.23 Surface		
5.24 Ground		
5.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		
6. MODE OF ACTION		

FORM A11,LIST II

FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use CIPAC methods for Physical/Chemical properties.

Summaries of the methods used and the results of toxicological and ecotoxicological studies, methods of analysis etc. should be given.

Numbering used in the dossier must correspond with that used in Form A9.

FORMULATED PRODUCT		
1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier if study included**	**Official use only**
1.2 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		

1.9 Density		
1.10 Bulk density		
1.11 Flammability		
1.12 Flash point		
1.13 Explosivity		
1.14 In-compatibility with other pest control Products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		
1.20 Wettability		
1.21 Solubility in water		
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Other properties (where applicable)		
1.29 Methods of Analysis		
2. TOXICOLOGY	**Annex No. in dossier if study included**	**Official use only**
2.1 Rat Acute oral LD_{50} mg/kg		

2.2 Acute dermal LD_{50} mg/kg		
2.3 Inhalation LD_{50} mg/l /hour		
2.4 Rabbit Skin irritation		
2.5 Eye irritation		
2.6 Sensitisation in guinea pig		
2.7 WHO classification		
2.8 Other studies		

	Annex No. in dossier if study included	**Official use only**
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
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		
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. USES (New label claims with this application)

FORMULATED PRODUCT	**Annex No. in dossier if study included**	**Official use only**
5.1 area of use		
5.2 Target organism		
5.3 Dosage		
5.4 Stage of treatment		
5.5 Directions for use		
5.8 Contraindications		
6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).		
7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medical surveillance, on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry..etc.		
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		

7.5 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.		

FORM A12

REPUBLIC OF KENYA

PEST CONTROL PRODUCTS ACT, CAP 346, 1982.

APPLICATION FOR THE REGISTRATION OF PLANT GROWTH REGULATORS AND POST HARVEST PRODUCTS FOR FLOWERS & ORNAMENTALS

Introduction

1. These guidelines are for any proposed use of plant growth regulators and post-harvest products on flowers and ornamentals.

2. Postharvest products for use on fruits and vegetables based on fungicides and insecticides shall follow guidelines provided under Form A

3. Where conventional pest control products (fungicide, herbicide, insecticide) are to be used as postharvest products either individually or in combination on cut flowers, then requirement provided on Form A List I will apply for the technical grade active ingredient.

4. Disinfectants for common use in public health, disinfecting working facilities and tools with no pesticidal claims are not covered in this guideline.

5. Dyes, leaf shiners and waxes used on cut flowers and ornamentals are not covered in this guideline

6. Hydrating agents (acidifiers, surfactants), sugars, non-ionic detergents are not covered in this guidelines

7. Information in support of a request for registration, both published and unpublished (fully cited) should be submitted

8. A pre-registration consultation between the applicant and the registration Board is strongly recommended.

Information for Applicants

1. The application form must be completed by a duly authorized person.

2. The application must be submitted in triplicate to:

The Managing Director/Secretary,

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

3. Every application must be accompanied by:-

a) application fee as prescribed (Registration fee is payable upon approval by the Board).

b) 3 copies of the draft label as per PCPB requirements.

4. The applicant may 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 a check list and an index to ensure that the applicant has

provided the relevant data.

6. The application must be accompanied by a technical dossier as per PCPB data

requirements (Lists I and II).

7. An applicant who is not a resident in Kenya must appoint an agent permanently resident

in Kenya and duly recognized by the Pest Control Products Board.

TRADE NAME……

PURPOSE OF APPLICATION (tick as appropriate)

a. Pest control product containing a new active ingredient	☐
b. Pest control product 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. Renewal of Registration	☐
f. Other (Explain) …… …… ……	

Will the product be marketed under own label? Yes ☐ No ☐ If no specify……..
Proposed date of marketing……

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

1.6 Fax: (and area code)			
1.7 e-mail:			
2. PRODUCT			
2.1 Designation (Description of product)	Trade name:		
	Trade mark:		
	Trade mark holder:		
2.2. Function of product: (plant growth regulator, postharvest products			
2.3 Specify intended use.			
2.4 Target organism (if any) & flower type e.g. Roses, Carnations etc.			
2.5 Method, dosage rates and frequency of application:			
2.6 Type of formulation: (e.g. EC, WP, etc.)			
2.7 a) Is the product registered in country of manufacture?	Yes ☐ No ☐ If no, give reasons if yes provide copy of certificate of Registration		
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ If no, give reasons if yes provide copy of certificate of Registration		

2.8 Registration in SEARCH[4] country/ies: (names)	
2.9 Existing registration No(s) and country(s).	
2.10 Customs Tariff Code: (Harmonized system Nomenclature)	

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. FORMULATION

4.1 Formulator: (Name)

Postal Address:

Physical address:

4.2 Internal code:

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

Ingredients and Function:	g/*l*	g/kg	Range

* Formerly GCPF

5. TOXICOLOGY (formulated product): See details in List II

[4]SEARCH - Southern and Eastern African Regulation Committee on Harmonization of Pesticide Registration

5.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} mg/kg)	Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
5.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
5.3 Skin Sensitization in guinea pig: (tick)		None ☐ Mild ☐ Moderate ☐ Severe ☐	

5.4 WHO classification:	Ia	Ib	II	III

5.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets

5.6 **Summary of environmental effects: see details in List I**

5.6.1 Toxicity to bees:	
5.6.2 Toxicity to fish and other aquatic organisms:	

5.6.3 Toxicity to birds:	
5.6.4 Toxicity to earthworms and soil micro-organisms:	
5.6.5 Toxicity to other non-target organisms:	
5.6.6 Persistence in environment:	
5.6.7 Other effects: Specify	
6. PACKAGING	
6.1 Packaging material / container:	
6.2 Pack size(s):	
6.3 Disposal of empty container(s):	
7. OTHER SPECIFIC REQUIREMENTS	
7.1 Operator exposure	
a). Dermal absorption.	
b). Likely operator exposure under field conditions	
c). Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).	
8. 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 is recognized by all SEARCH countries.

FORM A12, LIST I

ACTIVE INGREDIENT: DOSSIER INDEX

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, results of toxicological and ecotoxicological studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i)	**Annex No. in dossier if study included**	**Official use only**
1. **DESIGNATION/IDENTITY OF a.i.**		
1.1 Common name (ISO)		
1.2 Manufacturer or Development code		
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.4 Methods of manufacture s(synthesis pathways), may be sent direct to PCPB.		
1.5 Chemical name (IUPAC)		
1.6 Chemical group		
1.7 Structural formula		
1.8 Empirical formula		
1.9 Patent status		
Is the a.i. under patent?		
Who is patent holder		

Expiry date		
1.10 Molecular mass		
1.11CAS Number		

2. PHYSICAL AND CHEMICAL PROPERTIES

ACTIVE INGREDIENT	**Annex No. in dossier if study included**	**Official use only**
2.1 Physical state		
2.2 Colour		
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 DT_{50} ….. Days …… ^{0}C …… pH		
2.8 Photolysis		
2.9 Solubility in water ……^{0}C ……. pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point ^{0}C		
2.13 Melting point ^{0}C		
2.14 Decomposition temperature ^{0}C		
2.15 Method of Analysis and Impurities		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products		
2.17 Stability in organic solvents used in formulation		

ACTIVE INGREDIENT	Annex No. in dossier if study included	Official use only
2.18 Stability in air; effect of light, identity of breakdown Products		
2.19 Thermalstabilty, identity of breakdown product.		
2.20 Flammability		
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		

3. TOXICOLOGY

Data waivers are admissible for product designated as Food grade & Generally Regarded as Safe (GRAS) data waivers; Published literature/studies should be submitted. For non-food grade & Non GRAS 3.1-3.6 studies should be provided; the others 3.7-3,15 peer reviewed literature should be provided

ACTIVE INGREDIENT	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)		
3.3 Inhalation LC_{50} mg/l hour (rat)		
3.4 Skin irritation (rabbit)		
3.5 Eye irritation (rabbit)		
3.6 Skin sensitisation (guinea pig)		

ACTIVE INGREDIENT	**Annex No. in dossier if study included**	**Official use only**
3.7 Reproduction (specify species)		
3.8 Subchronic toxicity 90 day NOEL mg/kg/day		
3.9 Chronic toxicity NOEL mg./kg/day		
3.10 Carcinogenicity (life time) NOEL mg/kg/day		
3.11 Neurotoxicity NOEL mg/kg/day		
3.12 Teratogenicity NOEL mg/kg/day		
3.13 Mutagenicity /Genotoxicity		
3.14 Metabolism (rat)		
3.15 Other studies		

4. ACTIVE INGREDIENT

Food grade & Generally Regarded as Safe (GRAS) data waivers admissible. Published literature or studies should be submitted to address individual requirements listed.

ECO-TOXICOLOGY **(Active ingredient – technical grade**	**Annex No. in dossier** **if study included**	**Official use only**
4.1 Birds (2 species)	LD_{50} mg/kg	
	NOEL	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
4.2 Fish (2 species)	LD_{50} mg/kg	
	NOEL	
	LD_{50} mg/kg	

ECO-TOXICOLOGY **(Active ingredient – technical grade**	**Annex No. in dossier** **if study included**	**Official use only**
	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-organisms		

5. BEHAVIOUR IN ENVIRONMENT

Data waivers admissible for behavior, ways of degradation, degradation products in air if not intended for foliar application, non-volatile and used in controlled 'enclosed' environment. Published literature or studies should be submitted to address individual requirements listed

ECO-TOXICOLOGY **(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		

ECO-TOXICOLOGY **(Active ingredient – technical grade**	**Annex No. in dossier** **if study included**	**Official use only**
5.2 Behaviour, ways of degradation, degradation products in water		
5.21 Major Metabolites		
5.22 DT_{50} (days)		
5.23 Surface		
5.24 Ground		
5.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		
6. MODE OF ACTION		

FORM A10,LIST II

FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use CIPAC methods for Physical/Chemical properties. Summaries of the methods used and the results of toxicological and ecotoxicological studies, methods of analysis etc. should be given.Numbering used in the dossier must correspond with that used in Form A11.

1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier** **if study included**	**Official use only**
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source and specifications for components		

1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier if study included**	**Official use only**
included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		
1.9 Density		
1.10 Bulk density		
1.11 Flammability		
1.12 Flash point		
1.13 Explosivity		
1.14 In-compatibility with other pest control Products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		
1.20 Wettability		
1.21 Solubility in water		

1. PHYSICAL AND CHEMICAL PROPERTIES	**Annex No. in dossier if study included**	**Official use only**
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Other properties (where applicable)		
1.29 Methods of Analysis		

Toxicology:

Food grade &Generally Regarded as Safe (GRAS) data waivers admissible; Published literature/studies should be submitted; but where there are coformulants of toxicological concern the toxicological studies for the end use product should be provided. For non-food grade & Non GRAS Toxicological studies should be provided

2. TOXICOLOGY:	**Annex No. in dossier if study included**	**Official use only**
2.1 Rat Acute oral LD_{50} mg/kg		
2.2 Acute dermal LD_{50} mg/kg		
2.3 Inhalation LD_{50} mg/l /hour		
2.4 Rabbit Skin irritation		
2.5 Eye irritation		
2.6 Sensitization in guinea pig		
2.7 WHO classification		
2.8 Other studies		

	Annex No. in dossier if study included	Official use only
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
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		
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. USES (New label claims with this application)		
FORMULATED PRODUCT	**Annex No. in dossier if study included**	**Official use only**
5.1 Crop/area of use		
5.2 Rate		
5.3 Stage of treatment		
5.4 Target organism (if any)		
5.5 Directions for use		
5.6 Phytotoxicity		
5.7 Contra-indications		

5.8 Reentry intervals		
6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements		
7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medical surveillance on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry etc.		
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.		

FORM B

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY

Tel 020 4446115 or 020 4450242 Fax 020 4449072

E-MAIL: pcpboard@todays.co.ke

pcpboard@nbnet.co.ke

WEBSITE ADDRESS: www.pcpbkenya.org. or pcpb.or.ke

Summary of the data submitted to the PCPB for registration of a Conventional Pest Control Product.

PART I

Trade Name……

The Name and Address of Formulator……..

……

Common Name of the active ingredient(s), and concentration ……

……

……

……

Source(s) of a.i.(s) ……

Source(s) of formulation(s)
……

Chemical Name……..

……

Formulation type……..

Proposed Uses……..

……..

Packaging/Containers(Material size)……..

……..

Registrant (Name, Address, Status)……..

……..

Agents/Distributors in Kenya……

……..

Premises (License No., Date of issue)……

……..

PART II

CHEMISTRY DATA

a) Physical /Chemical Properties of the a.i……

……

……

b) Physical/Chemical properties of the technical grade material……..

……..

……

……

c) Composition of the technical product (purity%, nature and content of impurities, isomers, by-products)

……

……

……

d) Physical/Chemical Properties of the Formulated Product

……..

……

……

e) Composition of the Formulated Product……..

……..

……..

f) Method of analysis for determination of the a.i. in technical and formulated products

……..

……

PART III

Biological(efficacy) Data

a) Summarize the efficacy trial including the testing institution, number of seasons, period of testing

……..

……

b) Target Pest(s), Diseases(s), Host(s). Complete the efficacy GAP table below, in accordance with local efficacy data

GAP Table for Efficacy

1	3	4	5	6	7		8	10		11	12	13	14
Us	**Crop and/**	**Fungi**	**Pests or**	**Application**				**Application rate**				**PHI**	**Rema**

e-No.	**or situation** (crop destination / purpose of crop)	**cide/ Herbicide/Insecticide/ Others (specify)**	**Group of pests controlled** (additionally: developmental stages of the pest or pest Group, where necessary [e.g. larvae, adults])	Method / Kind	Timing / Growth stage of crop & season	Max. number of applications a) per use b) per crop or season	Min. interval between applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g/kg a.i/ha a) max. rate per appl. b) max. total rate per crop or season	g/kg of a.i. per hL min. -- max.	Water L/ha min / max	(days)	**rks:**
1	Indicator crop: (e.g.Tomato)	e.g. Fungicide	*Indicator pest(s):* *e.g. Phytophthorain festans*(late blight)	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days	
2	To be extrapolated to: Potato	F	*Phytophthorain festans*(late blight	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days	

c) Complete the crop safety GAP table below:

Crop safety assessment results

1		3	6	7			8	10		11	12	13	14
Use-No.	**Formulation details (a.i/L or Kg and formulation type)**	**Crop and/ or situation** (crop destination / purpose of crop)	**Application**									**Crop response**	**Remarks**
			Method / Kind	Timing / Growth stage of crop	Growing conditions (e.g. protected vs. outdoor)	Number of applications per season	Interval of applications	Product rate/ ha	g/kg a.i/ha	g/kg of a.i. per hL min. -- max.	Water L/ha		
1		Representative commodity: (e.g.To	Foliar spray	Flowering		3	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L		

1		3	6	7			8	10		11	12	13	14
Use-No.	**Formulation details (a.i/L or Kg and formulation type)**	**Crop and/ or situation** (crop destination / purpose of crop)	**Application**									**Crop response**	**Remarks**
			Method / Kind	Timing / Growth stage of crop	Growing conditions (e.g. protected vs. outdoor)	Number of applications per season	Interval of applications	Product rate/ ha	g/kg a.i/ha	g/kg of a.i. per hL min. -- max.	Water L/ha		
		mato)											

d) Recommendations for use in Kenya ……..

……..

e) Recommendations for use by authorized bodies outside Kenya……..

……..

PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

……..

……..

……..

b) Acute toxicity data of the formulated product:..

……...

……...

……..

c) Short term toxicity studies……...

……..

d) Other toxicological studies:

1) Reproduction studies ……..

……..

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……

4) Mutagenecity studies……..

……

5) Long term toxicity/carcinogenicity studies……..

……..

6) Accumulation of compound in tissues……

……

……

7) Metabolic studies……

……..

……

8) Effects on livestock, poultry……..

……

……

9) Toxicity Data on impurities……

……

……

10) Toxicity Data on metabolites……

……

……

11) Human toxicology and medical aspects:

1)Hazards to humans……..

……..

……..

2) Symptoms of poisoning……..

……

3) Antidote……

……..

4) Treatment ……

……..

5) First Aid Measures……

……..

……..

6) Safety Precautions/Restrictions……..

……..

……..

PART V – RESIDUE DATA

a) Principal Residues……

……..

……

b) Disappearance and fate of residues……..

……

……..

c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)……

……..

……..

d) Summary of results of supervised residue trials (Complete the GAP table for residues below. Use a different table for each crop group listed in the efficacy GAP table)

GAP table for residues

1	2	3	4	6	7		8	10		11	12	13	14	
Use-No.	**Country**	**Formulation details (a.i/L or Kg and formulation type)**	**Crop and/ or situation** (crop destination / purpose of crop)	**Application**								**PHI** (days) (days after last application)	**Results** (mg a.i/kg)	**Codex/EU MRL**
				Method / Kind	Timing / Growth stage of crop	Number of applications per season	Interval of applications	Product rate/ ha	g/kg a.i/ha	g/kg of a.i. per hL min. --max.	Water L/ha min / max			
1			Representative commodity: (e.g.Tomato)	Foliar spray	Flowering	3	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days		
			Trial 1											

1	2	3	4	6	7		8	10		11	12	13	14	
Use-No.	**Country**	**Formulation details (a.i/L or Kg and formulation type)**	**Crop and/ or situation** (crop destination / purpose of crop)	**Application**								**PHI** (days) (days after last application)	**Results** (mg a.i/kg)	**Codex/EU MRL**
				Method / Kind	Timing / Growth stage of crop	Number of applications per season	Interval of applications	Product rate/ ha	g/kg a.i/ha	g/kg of a.i. per hL min. - -max.	Water L/ha min / max			
			Trial 2											
			Trial 3											
			Trial 4											

PART VI

Environment and wildlife hazards

a) Degradation and mobility studies (soil,water, air) ……..

……...

b)Toxicity to birds……...

……

c)Toxicity to fish……

……..

d)Toxicity to honeybees/beneficial insects……

……..

e)Toxicity to earthworms, other soil invertebrates……

……

f)Changes in soil ecology……..

……

PART VII

Information on Approvals/Registrations in other countries……..

……

……

……

……

……

……

……

PART VIII

Draft of local label (as per Legal Notice No.89/1984).

……..

……..

……

PART IX

Brief prepared by:……

Signature:……

Official stamp

Date……..

PART X

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

……

……

……

Date……

FORM B1

PEST CONTROL PRODUCTS BOARD
P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel: 254-020 4446115/4450242 Fax: 254-020 4449072
E-MAIL: pcpboard@todays.co.ke
WEBSITE ADDRESS: www.pcpb.or.ke

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A MICROBIAL PEST CONTROL PRODUCT.

PART I

Trade Name……

Name of the manufacturer and address……

The Name and Address of Formulator……..

Common Name of the active Agent (s) ……

Concentration of active ingredient(s) ……

Source of active ingredient(s) ……

Scientific name of the microbial Agent……

Formulation type……

Proposed Uses……

Packaging/Containers (Material size)……

Agents/Distributors in Kenya……

Premises (Reg.No. Date of issue)……

PART II

PHYSICAL/CHEMICAL PROPERTY OF THE ACTIVE AGENT

a) Physical /Chemical Properties of the active agent……..

……

……

b) Physical/Chemical properties of the technical grade material add (incase different from point a) above)……..

……

……

……

c) Composition of the technical product (purity%, nature and content of impurities/contaminants, by-products – other details should be provided in the dossier)

……

……

……

d) Physical/Chemical Properties of the Formulated Product

……

……

……

e) Concentration of active agents. in the formulation. (Other details should be provided in the dossier)……..

……..

……..

f) Method of Identification, Enumeration and Bioassay

……..

……..

PART III

BIOLOGICAL PROPERTIES OF THE MICROOGANISM

a) Origin of microorganisms and its uses……

b) Effect in the non-target organisms……..

c) Life cycle of the microorganisms……..

d) Infectivity (plants and animals)……..

e) Dispersal and colonization……

f) Effect of environmental parameters (UV, temperature, soil pH, humidity, nutrition requirements, etc.) on stability and survival

g) Relationships to known plant, animal or human pathogens……

h) Genetic stability and factors affecting it(potential mutant)……..

i) Information on the production of metabolites (especially toxins)

j) Show antibiotics and other anti-microbial properties

PART IV

Biological (efficacy) Data

a) Target Pest(s), Diseases(s), Host(s)……..

b)Mode of action of the microorganism ……

c) Method, Rate, Frequency of application……

d) Recommendations for use in Kenya ……

e) Recommendations for use by authorized bodies outside Kenya……..

PART V

Toxicological data

a) Acute Toxicological/Infectivity Data of the active agent(s)

……..

……..

……..

b) Acute toxicity data of the formulated product:

……..

……..

……..

c) Short term toxicity studies (if there is concern under Tier 1 studies)……

……..

d) Other toxicological studies(if concerns on Tier 1 and 2**)……..**

1) Reproduction studies ……..

……

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……..

4) Long term toxicity/carcinogenicity studies……..

……

6) Metabolic studies (if microorganism organism is known to produce metabolites)……

……

……

7) Effects on livestock, poultry (if exposure is expected)……

……

……

8) Toxicity information on impurities/contaminants if pathogenic significant…….

……

……

9) Toxicity Data on metabolites (if applicable)……..

……..

……..

10) Human toxicology and medical aspects:

1)Hazards to humans……

……

……

2) Symptoms of poisoning or allergic reactions……..

……..

3) Antidote……

……..

4) Treatment ……

……..

5) First Aid Measures……

……..

……..

6) Safety Precautions/Restrictions……

……..

……..

PART VI – RESIDUE DATA

(Data is required if the microorganism produces metabolites)

a) Principal Residues……..

……

……

b) Disappearance and fate of residues……..

……..

……..

c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)……

……..

……..

PART VII

Environment and wildlife hazards

a) Degradation and mobility studies (soil, water, air) ……..

……

b)Toxicity to birds……

……..

c) Toxicity to fish…….. d) Effects on aquatic invertebrates……

e)Toxicity to honeybees/beneficial insects……..

……

f)Toxicity to earthworms, other soil invertebrates……..

……

g) Effect on other soil microorganisms……..

……

PART VIII

a) Information on Approvals by local phytosanitary authorities……

b) Registrations in other countries (Attach copies of certificates)

……..

c) Information on approval by national bio-safety Board if GMO's……

……

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……..

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……

……

<u>PART IX</u>

Draft of local label (as per Legal Notice No.89/1984).

……..

……..

……

PART X

Brief prepared by……

Signature……..

Official stamp ……..

Date……..

PART XI

Decision of the PCPB Technical and registration Committee

Recommended/Not Recommended for registration

Reasons:-

……

……

Date……

FORM B2

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY

Tel: 254-020 4446115/4450242 Fax: 254-020 4449072

E-MAIL: pcpboard@todays.co.ke

WEBSITE ADDRESS: www.pcpb.or.ke

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT.

PART I

Trade Name……

Collection Number (National museum of Kenya)……

The Name and Address of Formulator……..

……

Common Name of the active agent(s)

Description of unit……..

Counts of active agent(s) per unit ……

Source of active agent ……

Scientific name of the agent……

……

Form of presentation (stage of development, carrier material……

Proposed Uses……...

……..

Packaging/Containers (Material ,size)……...

……..

Registrant (Name, Address, Status)……..

……...

Agents/Distributors in Kenya……

……...

Premises (Reg.No. Date of issue)……

……..

PART II

BIOLOGICAL DATA

a) Description of the agent as presented (stage, colour,…)

b)Taxonomy……

c) Descriptive identification of the agent… ….

d) Natural occurrence and geographical distribution…..

e) Host specificity range and effects on non-target species…(including invasiveness, dispersal, colonization ability)

f) Development stages/life cycle

g)Genetic stability.

h) Stability in proposed packaging

i) Method of quantification

PART III

Efficacy Data

a) Target Pest(s), Diseases(s), Host(s). ……..

……..

b) Mode of action

b) Method, Rate, Frequency of application……..

……..

c) Recommendations for use in Kenya ……

……..

d) Recommendations for use by authorized bodies outside Kenya……..

……..

……

PART IV

Biosafety data

a) Bio-Surveillance data available

b) Relationships to known plant, animals or human parasites……..

c) Hazards to humans…….

d) Safety precautions/Restrictions

……

e) Recommended methods and precautions concerning handling, storage, or storage….

f) Procedures for destruction… ……..

g) Measures in case of an accident ……..

PART VI

Environmental Data

a) Effects of environmental parameters on stability and survival (UV, temperature, soil, pH, Humidity, etc) ……..

……

PART VII

a) Clearance by Phytosanitary Board

b) Registrations in other countries (Attach copies of certificates)

……..

……

PART VIII

Draft of local label (as per Legal Notice No.89/1984).

……..

……..

……

PART IX

Brief prepared by……

Signature……..

Official stamp ……..

Date……..

PART X

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

……

……

……

Date……

FORM B3

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY

Tel: 254-020 4446115/4450242 Fax: 254-020 4449072

E-MAIL: pcpboard@todays.co.ke

WEBSITE ADDRESS: www.pcpb.or.ke

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A BIOCHEMICAL PEST CONTROL PRODUCT.

PART I

Trade Name……

The Name and Address of manufacturer……

The Name and Address of Formulator……..

……

Common Name of the active ingredient(s)……..

Concentration of active ingredient(s)……

Source of active ingredient(s)……

Chemical Name……..

……

Formulation type……

Proposed Uses……..

……..

Packaging/Containers (Material size)……..

……..

Registrant (Name, Address, Status)……..

……..

Agents/Distributors in Kenya……

……..

Premises (Reg.No. Date of issue)……

……..

PART II

CHEMISTRY DATA

a) Physical /Chemical Properties of the a.i……

……

……

b) Physical/Chemical properties of the technical grade material……..

……..

……

……

c) Composition of the technical product (purity%, nature and content of impurities, isomers, by-products – other details should be provided in the dossier)

……..

……..

……..

d) Physical/Chemical Properties of the Formulated Product

……..

……..

……..

e) Composition of the Formulated Product (Concentration of a.i. in the formulation. other details should be provided in the dossier)……..

……..

……..

f) Method of analysis for determination of the a.i. in technical and formulated products

……..

……..

PART III

Biological(efficacy) Data

a) Target Pest(s), Diseases(s), Host(s). ……..

b) Mode of action……

c) Method, Rate, Frequency of application……..

……..

d) Recommendations for use in Kenya ……

……..

e) Recommendations for use by authorized bodies outside Kenya……..

……..

……

PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

……..

……..

……..

b) Acute toxicity data of the formulated product:..

……..

……..

……..

c) Short term toxicity studies……

……..

d) Other toxicological studies:

1) Reproduction studies ……..

……

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……..

4) Mutagenecity studies……..

……

5) Long term toxicity/carcinogenicity studies……..

……

6) Accumulation of compound in tissues……

……..

……..

7) Metabolic studies……

……

……

8) Effects on livestock, poultry……

……

……

9) Toxicity Data on impurities……

……

……

10) Toxicity Data on metabolites……..

……..

……..

11) Human toxicology and medical aspects:

1)Hazards to humans……

……

……

2) Symptoms of poisoning……..

……..

3) Antidote……

……..

4) Treatment ……

……..

5) First Aid Measures……

……..

……..

6) Safety Precautions/Restrictions……

……..

……..

PART V – RESIDUE DATA

a) Principal Residues……..

……

……

b) Disappearance and fate of residues……..

……..

……..

c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)…….

……..

……..

PART VI

Environment and wildlife hazards

a) Degradation and mobility studies (soil,water, air) ……...

……

b)Toxicity to birds……

……..

c)Toxicity to fish……..

……

d)Toxicity to honeybees/beneficial insects……..

……

e)Toxicity to earthworms, other soil invertebrates……..

……

f)Changes in soil ecology……..

……

PART VII

Information on Approvals/Registrations in other countries (Attach copies of certificates)

……..

……

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……

……..

……

……

PART VIII

Draft of local label (as per Legal Notice No.89/1984).

……..

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……

PART IX

Brief prepared by……

Signature……..

Official stamp ……..

Date……...

PART X

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

……

……

Date……

FORM B4
PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY

Tel: 254-020 4446115/4450242 Fax: 254-020 4449072

E-MAIL: pcpboard@todays.co.ke

WEBSITE ADDRESS: www.pcpb.or.ke

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A SEMIOCHEMICAL PEST CONTROL PRODUCT

PART I

1. Trade Name……

2. The Name and Address of Formulator……

……..

3. Common Name of the active ingredient(s)……

4. Concentration of active ingredient(s)……..

5. Source of a.i. (natural or synthetic)……..

6. Name & Location of producer of a.i……

7. Chemical Name……

8a. Formulation type……..

8b. Associated Device……

9. Proposed Uses……..

……..

10. Packaging/Containers (Material, size)……..

……..

11. Registrant (Name, Address,)……..

……..

12. Agent/Distributors in Kenya……..……..

……..

13. Premises (Registration .No. Date of issue)……..

……

PART II

CHEMISTRY DATA

14 a) Physical/Chemical properties of the technical grade material……..…

……

……

b) Composition of the technical product (purity %, natures & identity of impurities – other details should be provided in the dossier).

……

……

c) Physical/Chemical Properties of the Formulated Product

……

……

d) Composition of the Formulated Product (Concentration of a.i. in the formulation. Other details should be provided in the dossier)……..

……

……

e) Method of analysis for determination of the a.i. in technical and formulated products

(State all the methods for different components)

……

……

PART III

BIOLOGICAL EFFICACY DATA

a) Target Pest(s), Host(s). ……..

……..

b) Mode of action……

c) Method, Rate, Frequency of application……..

……..

d) Recommendations from local biological efficacy trials for use in Kenya
……

……..

e) Recommendations for use by authorized bodies outside Kenya……..

……..

……

PART IV

TOXICOLOGICAL DATA

A) Technical grade active ingredient(s)

TIER I Requirements

a) Acute Toxicological Data of the Technical grade active ingredient(s)
Straight-Chain Lepidopteran Pheromones (SCLPs) are exempt from all toxicological data requirements. The following studies are required for non- SCLPs

Acute oral LD_{50}……

Acute dermal LD50……..

Inhalation LC_{50}……

……..

……..

b) Short term toxicity studies……

……..

c) Mutagenecity studies

TIER II Requirements (Information is required if concerns are triggered by TIER I studies.

1) Reproduction studies ……..

……

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……..

4) Additional mutagenicity studies……..

……

5) Carcinogenicity studies……..

……

6) Chronic toxicity……...

……..

7) Hypersensitivity/allergies in human or any other human exposure data

……

8) Metabolic studies……

……

……

……

B) Acute toxicity data of the formulated product:

SCLPs are exempt provided the co-formulants are not of toxicological concern (MSDS must be provided). The Acute toxicity studies will be provided for non-SCLPs if any of the co-formulants are of toxicological concern.

……..

……..

PART V

EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING

a) Hazards to humans……

……..

……

b) Symptoms of poisoning……..

……..

c) Antidote……

……

d) Treatment ……

……..

e) First Aid Measures……..

……..

……...

f) Safety Precautions/Restrictions……

……..

……..

PART VI

ECO-TOXICOLOGY

a) Toxicity to birds (Required if the product could be ingested by birds, e.g. a granular formulation) ……..

……..

b) Toxicity to fish (Required if product is applied by air, or directly to water or at a rate exceeding natural background levels)

……..

c) Freshwater invertebrates (Required if product is applied by aircraft, or directly to water or at a rate exceeding natural background levels)

……

d) Algae (Waived for products in affixed dispensers and if exposure is unlikely to exceed natural background levels)……..

……..

e) Toxicity to bees (Information/discussion, to address whether behaviou0r or reproduction would be affected, is required if exposure is likely to exceed natural background levels) ……..

……

f) Toxicity to earthworms (Required if product is applied to soil and can accumulate in soil. Required if exposure exceeds natural background levels)

……

……

PART VII

Information on Approvals/Registrations in other countries (Attach copies of certificates)……..

……..

……..

PART VIII

Draft of local label (as per Legal Notice No.89/1984).

……..

PART IX

Brief prepared by……

Signature……..

Official stamp ……..

Date……..

PART X (For official use only)

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

Date……

FORM B5

PEST CONTROL PRODUCTS BOARD

P.O. Box 13794, 00800 Nairobi,

E-mail address info@pcpb.go.keTel.254-2-8021846/7/8,

Fax 254-2-8021865

WEBSITE ADDRESS:

https://www.pcpb.go.ke/

Summary of the data submitted to the PCPB for registration of a Pest Control Productfor use in paint for in-can and film preservatives

PART I

Trade Name……

The Name and Address of Formulator……..

……

Common Name of the active ingredient(s) [a.i] and concentration ……

……

……

……

Source(s) of a.i.(s) ……

Source(s) of formulation……

Chemical Name……..

……

Formulation type……..

Proposed Uses……..

……..

Packaging/Containers (Material, size)……..

……..

Registrant (Name, Address, Status)……..

……..

Agents and Distributors in Kenya……

……..

Premises (License No., Date of issue)……

……..

PART II

CHEMISTRY DATA

a) Physical /Chemical Properties of the a.i……

……

……

b) Physical/Chemical properties of the technical grade material……..

……..

……

……

c) Composition of the technical product (purity%, nature and content of impurities, isomers, by-products)

……

……

……

d) Physical/Chemical Properties of the Formulated Product

……..

……

……

e) Composition of the Formulated Product……..

……..

……..

f) Method of analysis for determination of the a.i. in technical and formulated products

……..

……

PART III

Biological (efficacy) Data

a) Target Pest(s), Host(s). ……

……

b) Method, dosage, Frequency of application……

…… ……

c) Recommendations for use in Kenya ……..

……..

d) Recommendations for use by authorized bodies outside Kenya……..

……..

……..

PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

……..

……..

……..

b) Acute toxicity data of the formulated product:..

……..

……..

……

c) Short term toxicity studies……..

……

d) Other toxicological studies:

1) Reproduction studies ……..

……..

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……

4) Mutagenecity studies……..

……

5) Long term toxicity/carcinogenicity studies……..

……..

6) Accumulation of compound in tissues……

……

……

7) Metabolic studies……

……..

……

8) Effects on livestock, poultry……..

……

……

9) Toxicity Data on impurities……

……

……

10) Toxicity Data on metabolites……

……

……

11) Human toxicology and medical aspects:

1) Hazards to humans……..

……..

……..

2) Symptoms of poisoning……..

……

3) Antidote……

……..

4) Treatment ……

……..

5) First Aid Measures……

……..

……..

6) Safety Precautions/Restrictions……..

……..

……..

PART V

Environmental hazards

a) Degradation and mobility studies (soil, water, air) ……..

……..

b)Toxicity to birds……..

……

c) Toxicity to fish……

……..

d)Toxicity to honeybees/beneficial insects……

……..

e)Toxicity to earthworms, other soil invertebrates……

……

f) Changes in soil ecology……..

……

PART VI

Information on Approvals/Registrations in other countries (attach copies of certificates)……..

……

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……

PART VII

Commercial local label (as per Legal Notice No.89/1984 and 127 /2006).

……..

……..

……

PART VIII

Brief prepared by:……

Signature:……

Official stamp

Date……..

PART IX

Decision of the PCPB technical and registration Committee

Recommended/Not recommended for registration

Reasons:-

……

……

……

Date……

FORM B6
PEST CONTROL PRODUCTS BOARD

P.O. Box 13794 - 00800 Nairobi.

E-mail address:

info@pcpb.go.ke/md@pcpb.go.ke

Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865

WEBSITE ADDRESS:

https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF PLANT GROWTH REGULATORS AND POST HARVEST PRODUCTS FOR FLOWERS & ORNAMENTALS

PART I

1. Trade Name……

2. The Name and Address of Formulator……..

……

3. Common Name of the active ingredient(s)……..

4. Concentration of active ingredient(s)……

5. Name & Location of manufacturer of technical grade active ingredient……

7. Chemical Name……..

8. Formulation type……..

9. Proposed Uses……..

……..

10. Packaging/Containers (Material, size)……..

……..

11. Registrant (Name, Address, Status)……..

12. Agents/Distributors in Kenya……..……

……..

13. Premises (Reg.No. Date of issue)……

……..

PART II

CHEMISTRY DATA

14. Physical /Chemical Properties of the a.i……

……

……

b) Physical/Chemical properties of the technical grade material……..

……..

……

c) Composition of the technical product (purity %, natures & identity of impurities – other details should be provided in the dossier)

……..

……...

d) Physical/Chemical Properties of the Formulated Product

……..

e) Composition of the Formulated Product (Concentration of a.i. in the formulation. other details should be provided in the dossier)……..

……...

f) Method of analysis for determination of the a.i. in technical and formulated products (State all the methods for different components)

……..

……..

PART III

Biological(efficacy) Data

a) Area of use/Target Organism (if any), flower type(s).

……..

b) Mode of action……..

c) Method, Rate, Frequency of application……..

……..

d) Recommendations for use in Kenya ……

……..

e) Recommendations for use by authorized bodies outside Kenya……..

……..

PART IV

Toxicological data

Food grade & Generally Regarded as Safe (GRAS) data waivers admissible; include summaries from Published literature or studies.

For non food grade & Non GRAS provide acute toxicological study summaries. For long term study summaries from peer reviewed literature should be included

a) Acute Toxicological Data of the active ingredient(s)

……..

……..

b) Acute toxicity data of the formulated product:..

……..

c) Short term toxicity studies……

……..

d) Other toxicological studies:

1) Reproduction studies ……..

……

2) Teratological studies……

……..

3) Neurotoxicity studies……..

……..

4) Mutagenecity studies……..

……

5) Long term toxicity/carcinogenicity studies……..

……

6) Accumulation of compound in tissues……

……..

……..

7) Metabolic studies……

……

8) Effects on livestock, poultry……

……

9) Toxicity Data on impurities……

……

10) Toxicity Data on metabolites……..

……..

11) Human toxicology and medical aspects:

1) *Hazards to humans*……

2) Symptoms of poisoning……

3) Antidote……

4) Treatment ……

5) First Aid Measures……

6) Safety Precautions/Restrictions……

PART V: Environment and wildlife hazards

Summaries from published literature or studies should be included to address individual requirements

a) Degradation and mobility studies (soil, water, air) ……..

……

b)Toxicity to birds……

……..

c)Toxicity to fish……..

……

d)Toxicity to honeybees/beneficial insects……..

……

e)Toxicity to earthworms, other soil invertebrates……..

……

f)Changes in soil ecology……..

……

PART VI

Information on Approvals/Registrations in other countries (*attach copy of certificate of Registration)*

PART VII

Draft of local label (as per Legal Notice No.89/1984).

……..

PART VIII

Brief prepared by……

Signature……..

Official stamp ……..

Date……...

PART IX

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

……

Date……

FORM C

PEST CONTROL PRODUCTS BOARD

THE PEST CONTROL PRODUCTS ACT CAP 346 OF 1982

EXPERIMENTAL PERMIT

Date……

Accredited testing institution

Address

Tel: ……

Email: ……..

PERMIT FOR EFFICACY TRIALS OF NEW PEST CONTROL PRODUCTS

This is to request your organization to carry out efficacy trials of the newly introduced pest control product (s) as indicated below:-

Pest Control Product(s) (Trade name)	**Common name & concentration of a.i**	**Crop(s)/Commodity (ies)/ Use(s)**	**Target Pest(s)**

You are requested to inform the Pest Control Products Board the commencement of the experiment/efficacy trials and submit to the Board progress reports. The trials should be carried out using the Pest Control Products Board approved trial protocol. At the conclusion of the experiment/efficacy trials, a confidential report on the

performance of the product and recommendations for its use should be submitted to the Board quoting the **above reference and date.**

It will be appreciated if trials are completed as soon as possible. **Local agent** will provide you with the required materials and financial resources for the trials. ***All companies must apply for an import license for the trial sample which should be submitted directly to the Board for onward transmission to the researchers. The trial samples should neither be sold nor used elsewhere without Board from PCPB.***

Local agent is advised to liaise closely with you and PCPB to ensure that the tests are carried out in accordance with the approved trial protocol.

CHIEF EXECUTIVE OFFICER /SECRETARY

cc. Local agent

Address

***Note**: All applicants are expected to submit the Pre-harvest interval (PHI) and Maximum Residue Levels (MRLs) for all edible crops.*

Form D1.

CONFIDENTIAL BUSINESS INFORMATION SUBMISSION/RECEIPT FORM

		Provided		**Remarks**
		Yes	**No**	
1	Method of manufacture (e.g. synthesis pathway)			
2	Specifications of the technical grade (active ingredient)			
3	Composition of the formulation			
4	Method of analysis for impurities			
5	'5-batch' analysis; including chromatographs			
6	Any other information			

Date received	
Trade name of the Product	
Active ingredient(s)	
Registrant	
Manufacturer(s) of active ingredient	
Formulator	
Exporter	
Local agent	
Submitted by (**Full Name andsignature)***	
Received by: **Officer's name andsignature**	

Handed over to the **Head of department.** **Signature:**	

**** Confidential business information received as it is subject to technical evaluation.***

Form D2

CONFIDENTIALITY DECLARATION

I……from ……..(*company oflocal agent, representative*) declare that I shall maintain confidentiality of all Confidential Business information (CBI) as provided for under the Pest Control Products Act and Regulations made thereunder.

Signature……..

Name of agent/representative

Designation

Date……..

Republic of Kenya

FORM E

PEST CONTROL PRODUCTS BOARD

(Statutory Organization of Government of Kenya)

THE PEST CONTROL PRODUCTS ACT CAP 346 OF 1982

Certificate of Registration of A Pest Control Product

Number ……

It is hereby certified that the pest control product described herein has been registered under the Pest Control Product Act and is subject to conditions indicated-

1. Approved common name ……..
2. Trade name under which marketed in Kenya ……..

   ……
3. Active ingredient(s) ……..
   ……
4. Formulation ……
5. Condition(s) under which pest control product is registered
   ……..
   ……
   ……
6. Registration No. ……..
7. Registration in the name of ……

   ……..

   Address……Email……..

   Tel. No. ……
8. Date of registration ……
9. Date of registration expires ……

…… ……

Chairman Secretary

Pest Control Products Board Pest Control Products Board

FORM F

PEST CONTROL PRODUCTS BOARD

CHANGE OF SOURCE

PRODUCT INFORMATION

1. Trade Name:……
2. Common name of active ingredient(s) and Concentration:……
3. PCPB Registration No:……
4. Technical Grade Active Ingredient (Current source)
    (a) Name of basic manufacturer:……
    (b) Physical Location of basic manufacturer:……
    (c) Address:
        (i) Postal Address:……..
        (ii) Telephone No:……..
        (iii) E-Mail:……
        (iv) Fax No:……..
        (v) Street/Road:……
    (d) Specifications (Certificate of composition)
    (e) Relationships with Registrant, if different

5. Technical Grade Active Ingredient (New source)

   (a) Name of basic manufacturer:……

   (b) Physical Location of basic manufacturer:……

   (c) Address:
      (i) Postal Address:……..

      (ii) Telephone No:……...

      (iii) E-Mail:……

      (iv) Fax No:……...

      (v) Street/Road:……

   (d) Specifications (with analytical proof-5 batch analysis)
   (e) Relationships with Registrant, if different

6. Formulated Product

   (a) Name of Formulator:……..

   (b) Physical Location:……

   (c) Address
      (i) Postal Address: ……

      (ii) Telephone No: ……

      (iii) Fax No:……..

      (iv) E-Mail: ……

      (v) Street/Road: ……

   (d) **Composition** (with analytical proof)

(e) Relationship with the registrant

7. Reason for change of manufacturer/Formulator.

NB: Fill separate form for each basic manufacturer/formulator, if more than one.

SECOND SCHEDULE

ITEMS EXEMPTED FROM REGISTRATION

1. Garment bags, cabinets or chests that are manufactured, represented or sold as a means to protect clothing or fabrics from pests.
2. Electronic apparatus that is manufactured, represented or sold as a means to attract or destroy flying insects.
3. Devices of products that are manufactured, represented or sold to repel birds and other pests by causing physical discomfort by means of sound or touch.
4. Devices of attachment to garden watering hoses that are manufactured, represented or sold as pest control product.
5. Devices that are manufactured, represented or sold as a means of providing the automatic or unattended application of a pest control product.
6. Devices that are sold for use with chemical products containing cyanide as a means to control animal pests.
7. Devices that are meant to control any pest through physical or mechanical means provided that there are no known environmental hazards expected from the use of the device.