

FORM A4



**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 authority 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: pcpboard@todays.co.ke/md@pcpb.or.ke**  
**Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865**  
**Website: www.pcpb.or.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.

**TRADE NAME.....**

**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	<input type="checkbox"/>
c. Registration transfer	<input type="checkbox"/>
d. Amendments to existing registration (e.g inerts, source of technical material e.t.c)	<input type="checkbox"/>
e. Other (Explain) .....	
.....	
.....	

f. Will the product be marketed under own label?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If no specify.....		
Proposed date of marketing.....		

<b>1. APPLICANT</b>	
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:	

<b>3</b>	<b>PRODUCT</b>		
3.1	Designation (Description of product)	Trade name:	
		Trade mark:	
		Trade mark holder:	
3.2	Function of product: (eg. Insecticide, herbicide etc.)		
3.3	Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc.)		
3.4	Target pest(s) and host(s)		
3.5	Method, dosage rates and frequency of application:		
3.6	Type of formulation: (eg. EC, WP, etc.)		CropLife International(CLI*) Code (if available)

\* Formerly Global Crop Protection Federation (GCPF)

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



6.1 Rat:	Acute Oral (LD <sub>50</sub> mg/Kg)	Acute Dermal (LD <sub>50</sub> mg/Kg)	Inhalation LC <sub>50</sub> (mg/L/4 hour)
	Experimental	Experimental	Experimental
6.2 Rabbit:	Skin irritation	Eye irritation	
	None		
	Mild		
	Moderate		
	Severe		
6.3 Skin Sensitization in guinea pig: (tick)	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/>		
6.4 WHO classification:	Ia	Ib	II
			III
			Table V
6.5	Summary of other mammalian toxicological studies: eg. Livestock, wildlife, poultry, pets		

<b>7 Summary of environmental effects</b>	
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	

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

<b>9. OTHER SPECIFIC REQUIREMENTS</b>
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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).

<b>10. DECLARATION</b>	
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	<b>FOR OFFICIAL USE</b>
	Remarks ..... ..... ..... ..... Signed: ..... Date: .....

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

**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.

<b>ACTIVE INGREDIENT (a.i)</b>	<b>Annex No. in dossier if study included</b>	<b>Official use only</b>
<b>1. DESIGNATION/IDENTITY OF a.i.</b>		
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°C		
2.5 Vapour pressure at 20/25°C		
2.6 Volatility		
2.7 Hydrolysis DT <sub>50</sub> ..... Days ..... °C ..... pH		
2.8 Photolysis		
2.9 Solubility in water .....°C ..... pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point °C		
2.13 Melting point °C		
2.14 Decomposition temperature °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 stability, 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) <sup>1</sup>		

**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 <sub>50</sub> mg/Kg rat/rabbit		
3.3 Acute dermal LD <sub>50</sub> mg/Kg (rat)		
3.4 Inhalation LC <sub>50</sub> 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		
3.10 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**

<b>ECO-TOXICOLOGY (Active ingredient – technical grade)</b>	<b>Annex No. in dossier if study included</b>	<b>Official use only</b>
4.1 Birds (2 species)		
LD <sub>50</sub> mg/Kg		
NOEL		
Reproduction		
LD <sub>50</sub> mg/Kg		
NOEL		
Reproduction		
4.2 Fish (2 species)		
LD <sub>50</sub> mg/Kg		
NOEL		
Reproduction		
BCF		
LD <sub>50</sub> mg/Kg		
NOEL		
Reproduction		
BCF		
4.3 Daphnia		

<sup>1</sup> Technical equivalence – refer to dossier index

LC <sub>50</sub> mg/L		
NOEL		
4.4 Algae		
EC <sub>50</sub> mg/L (96 hours)		
4.5 Bees		
LD <sub>50</sub>		
µg/bee		
4.6 Earthworms		
LC <sub>50</sub> mg/Kg		
4.7 Soil micro-organisms		

**5. BEHAVIOUR IN ENVIRONMENT**

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

<b>6. RESIDUES</b>		
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		

<b>7. MODE OF ACTION</b>		

<b>8. OTHER SPECIFIC REQUIREMENTS</b>		
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 A4, 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.

<b>FORMULATED PRODUCT</b>		
<b>1. PHYSICAL AND CHEMICAL PROPERTIES</b>	<b>Annex No. in dossier if study included</b>	<b>Official use only</b>
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)		
<b>2. TOXICOLOGY</b>		
2.1 Rat Acute oral LD <sub>50</sub> mg/Kg		

2.2	Acute dermal LD <sub>50</sub> mg/Kg		
2.3	Inhalation LC <sub>50</sub> 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.

	<b>Annex No. in dossier if study included</b>	<b>Official use only</b>
<b>3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING</b>		
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	

<b>4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE</b>		
4.1	Fire fighting measures	
4.2	Procedures in case of spillage	

<b>5. BIOEFFICACY/USES (New label claims with this application)</b>		
	<b>Annex No. in dossier if study included</b>	<b>Official use only</b>
5.1	Crop/livestock/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	
5.7	Provide Efficacy data from similar climatic zones	
5.8	Phytotoxicity	
5.9	Contraindications	

<b>6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).</b>
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<b>7. OTHER SPECIFIC REQUIREMENTS</b>		
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	

<p>7.4 Procedures of destruction and decontamination of pest control product and its packaging</p> <ul style="list-style-type: none"><li>• Possibility of neutralization</li><li>• Controlled discharge</li><li>• Controlled incineration</li><li>• Water purification</li><li>• Procedures of cleaning application equipment</li><li>• Recommended methods and precautions concerning handling, storage, display or transport.</li></ul>		
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**GUIDELINE: ACTIVE INGREDIENT DOSSIER**

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

Proprietary rights are fully respected and the data kept secure indefinitely, but to support generic registrations the PCPB may access the original data after the lapse of the patent, to evaluate the conformity of the equivalent generic product.

**ACTIVE INGREDIENT (TECHNICAL GRADE)**

**1. DESIGNATION**

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>
<b>1. DESIGNATION/IDENTITY OF a.i.</b>	Specify accordingly.
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.	The method of manufacture, including the identity of the starting materials, the chemical pathways involved, and the identity of the by-products and impurities present in the final product, must be provided, for each manufacturing plant.
1.4 Methods of manufacture (synthesis pathways)	
1.5 Specifications of purity supported by random "5" batch analysis from GLP certified laboratory	The minimum content in g/Kg or g/L of pure active substance must be reported. Identity of isomers and/or impurities together with their structural formula and content expressed as g/Kg or g/L must be reported. Detailed results of analysis including chromatograms and description of equipment used etc must be provided.

<p>1.6 Active ingredient content supported by random “5” batch analysis from GLP certified laboratory</p>	<p>Representative samples of the active substance must be analysed for content of pure active substance, inactive isomers, impurities and additives, as appropriate. The analytical results reported must include quantitative data, in terms of g/Kg or g/L content, for all components present in quantities of more than 1 g/Kg or g/L and typically should account for at least 98% of the material analysed. The actual content of components which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties, must be determined and reported. Data reported must include the results of the analysis of individual samples and a summary of that data, to show the minimum and typical content of each relevant component, as appropriate.</p> <p><b>ACTIVE SUBSTANCE CONTENT</b></p> <p>The declared (nominal) active substance content must be stated with tolerance limits. The content must be declared in terms of pure active substance, not technical material. This nominal target must be declared label content.</p> <p>It is recognized that the active substance content will have a tolerance on content. The tolerances normally take into account only manufacturing, sampling and analytical variations and refer to the mean analytical result obtained, except where an overage is required. Positive deviations from the upper limits will be needed if the preparation is manufactured with an overage. However, where an overage is proposed this must be justified and evidence must be submitted that the breakdown of the active substance does not lead to hazardous products or adversely affect the safety or efficacy of the preparation.</p> <p>Where an FAO specification is available for an active substance in a preparation, the tolerance limits must meet those in the FAO specification. However where there is no appropriate FAO specification the following guideline tolerances as accepted by the FAO are applicable.</p> <table border="1" data-bbox="813 1545 1428 1982"> <thead> <tr> <th data-bbox="813 1545 1125 1612">Declared content g/Kg or g/L at 20° C</th> <th data-bbox="1125 1545 1428 1612">tolerance</th> </tr> </thead> <tbody> <tr> <td data-bbox="813 1612 1125 1982">Up to 25</td> <td data-bbox="1125 1612 1428 1982">                     ± 15% of the declared content for homogenous preparations (liquid preparations e.g EC, SC, SL)                      ± 25% of the declared content for non-homogenous preparations (solid preparations e.g. GR, WG)                 </td> </tr> </tbody> </table>	Declared content g/Kg or g/L at 20° C	tolerance	Up to 25	± 15% of the declared content for homogenous preparations (liquid preparations e.g EC, SC, SL) ± 25% of the declared content for non-homogenous preparations (solid preparations e.g. GR, WG)
Declared content g/Kg or g/L at 20° C	tolerance				
Up to 25	± 15% of the declared content for homogenous preparations (liquid preparations e.g EC, SC, SL) ± 25% of the declared content for non-homogenous preparations (solid preparations e.g. GR, WG)				

	above 25 up to 100	± 10% of the declared content
	above 100 up to 250	± 6% of the declared content
	above 250 up to 500	± 5% of the declared content
	above 500	± 25 g/Kg or g/L of the declared content
	<p>Where the proposed tolerance limits for an active substance are outside the above ranges then this must be fully justified.</p> <p>Where an active substance is present as an ester or a salt, the active substance content must be expressed as the amount of the ester or salt present (as the technical material) with a statement declaring the amount of the active principle</p> <p>e.g. 'x g/L or g/Kg of the salt/ester which is equivalent to y g/L or g/Kg of the free acid.'</p> <p>For hydrated salts such as ferrous sulphate the active substance content must be declared in terms of the amount of hydrated salt present with a statement declaring the amount of the anhydrous form present.</p> <p>e.g x g/Kg of ferrous sulphate heptahydrate equivalent to y g/kg anhydrous ferrous sulphate.</p>	
1.7	Chemical name (IUPAC)	Specify accordingly
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**  
(active ingredient – technical grade)

REQUIREMENTS:	REMARKS:
2.1 Physical state	Where relevant indicate method/test used.
2.2 Colour	
2.3 Odour	
2.4 Density at 20°C	
2.5 Vapour pressure at 20/25°C	
2.6 Volatility	
2.7 Hydrolysis DT <sub>50</sub> ..... Days ..... °C pH	Give the DT <sub>50</sub> of the active ingredient, with mention of temperature and pH parameters employed during the determination.
2.8 Photolysis	Give the DT <sub>50</sub> of the active ingredient (in days).
2.9 Solubility in water .....°C ..... pH	Where relevant indicate method/test used.
2.10 Solubility in organic solvents	
2.11 n-octanol/water partition coefficient	
2.12 Boiling point °C	
2.13 Melting point °C	
2.14 Decomposition temperature °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 stability, identity of breakdown product.	Where relevant indicate method/test used.
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. TOXICOLOGY**  
**(Active Ingredient – technical grade)**

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

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>
NOEL	Non observable effect level (expressed in mg product / Kg weight on animal)
<b>Short term toxicity</b>	
Oral cumulative toxicity (28 days study)	Not mandatory, but can be useful.
Sub-chronic toxicity test of 90-day duration.	Oral route on two species – one rodent(rat) and one non-rodent.
Dermal route – 28-days dermal, 90-days dermal.	Specify accordingly.
Inhalation route 28-days inhalation, 90-days inhalation.	Specify accordingly.
3.1 ADI	Acceptable Daily Intake in mg product / Kg body weight
3.2 Acute oral LD <sub>50</sub> mg/Kg rat/rabbit	
3.3 Acute dermal LD <sub>50</sub> mg/Kg (rat)	
3.4 Inhalation LC <sub>50</sub> mg/L 4hour (rat)	
3.5 Skin irritation (rabbit)	
3.6 Eye irritation (rabbit)	
3.7 Skin sensitisation (guinea pig)	
3.8 Reproduction (specify species)	
3.9 Subchronic toxicity 90 day NOEL mg/Kg/day	
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. ECO-TOXICOLOGY**

Provide either an executive summary or individual summaries of studies on the behaviour of the pest control product in the environment. Provide information requested for in the application form.

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>	
4.1 Birds (2 species)	LD <sub>50</sub> mg/Kg	Provide details of at least one land and one water bird, LD <sub>50</sub> in mg product/Kg bird weight and the NOEL. Furthermore provide information on the effect on reproduction.
	NOEL	
	LD <sub>50</sub> mg/Kg	
	NOEL	
	Reproduction	

4.2 Fish (2 species)	LD <sub>50</sub> mg/Kg	Provide details on at least two species studied, LC <sub>50</sub> (in mg of product / litre of water) and the NOEL. Furthermore provide information on the effect on reproduction. Indicate the bioconcentration factor (BCF) on the active ingredient in tissues.
	NOEL	
	LD <sub>50</sub> mg/Kg	
	Reproduction	
	BCF	
4.3 Daphnia	LC <sub>50</sub> mg/L	Specify and provide details on other organisms according to the information requested on the form.
	NOEL	
4.4 Algae	EC <sub>50</sub> mg/L	
4.5 Bees	LD <sub>50</sub> µg/bee	
	NOEL	
4.6 Earthworms	LC <sub>50</sub> mg/Kg	
4.7 Soil micro-organisms		

**5. BEHAVIOUR IN ENVIRONMENT  
(active ingredient – technical grade)**

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

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>
<b>5.1 Behaviour, ways of degradation, degradation products in soil:</b>	<b>Indicate the degradation path of the active ingredient in the soil and the degradation products formed.</b>
5.1.1 Major metabolites	Specify the major metabolites in the soil and their behaviour.
5.1.2 DT <sub>50</sub> (days)	Specify the half-life of the active ingredient in various types of soils.
5.1.3 Mobility of the a.i.	Specify the degree of mobility of the active ingredient in the soil hence leaching potential and possibility for ground water contamination. If high, provide details on further studies i.e. lysimeter study.
5.1.4 Adsorption	Indicate the degree of adsorption of the active ingredient in the soil.
5.1.5 Mobility of metabolites	Indicate the degree of mobility of the metabolites in the soil.
<b>5.2 Behaviour, ways of degradation, degradation products in water:</b>	<b>Describe ways and speed of degradation of the active ingredient in water.</b>
5.2.1 Major Metabolites	Specify the major break down products formed and their adsorption/desorption on sediments.
5.2.2 DT <sub>50</sub> (days)	Specify the half-life of the active ingredient in water
5.2.3 Surface water	Describe ways and speed of degradation in surface and ground water. Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
5.2.4 Ground water	
<b>5.3 Behaviour, ways of degradation, degradation products in air:</b>	<b>Describe ways and speed of degradation in air and break down products formed. (for fumigants and volatile products).</b>

**6. RESIDUES**

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

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>
6.1 Major metabolites	Provide either an executive summary or individual summaries of studies conducted concerning the metabolites in plants. . Specify the metabolites . State their toxicological effects.
6.2 Metabolism	Describe the principle of metabolization of the active ingredient in the plant and the degradation products formed.
6.3 Behaviour of residues	Indicate the action and the persistence of the metabolites in the plant and animals.
6.4 MRL codex or other certified sources	MRL's (if available) When available state for each crop or vegetable product, the Maximum Residue Limit (MRL) recommended by the Codex Alimentarius Commission, two effective MRL's in two different countries and the MRL proposed in the country of application. If the proposed crop is to be exported provide detailed information in the dossier on MRL or import tolerances in the countries exported to.
6.5 Proposed PHI	
6.6 Method of residue analysis	Provide a copy in the dossier.

**7. MODE OF ACTION**

Must be explained in full to include where relevant the biochemical and physiological mechanism(s) and biochemical pathways involved

**8. OTHER SPECIFIC REQUIREMENTS**

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

**GUIDELINE: FORMULATED PRODUCT DOSSIER**

**1. PHYSICAL AND CHEMICAL PROPERTIES OF THE FORMULATED PRODUCT.**

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

<b>REQUIREMENTS:</b>	<b>REMARKS:</b>
1.1 Source, Name and Address of formulator and address and location of formulation plant.	The name and address of the formulator or formulators must be provided as must the name and address of each formulating plant. Where there are changes in the location of or number of formulators the prior consent of PCPB must be sought.
1.2 Source, MSDS and specifications of components included in the formulation.	Formulation components must where possible, be identified by their chemical name in accordance with IUPAC and CA nomenclature. Their structure or structural formula should be provided. Where the information provided does not fully identify a formulant, an appropriate specification must be provided. The trade name of formulants, where they exist, must also be provided.
1.3 Physical state / formulation type	Solid, liquid etc.
1.4 Colour	
1.5 Odour	
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation	
1.7 Storage stability	Indicate the stability of the preparation after storing at 54°C for 14 days. Other durations and/or other temperatures (e.g. 8 weeks at 40°C, 18 weeks at 30°C) if the preparation is thermo-sensitive.
1.8 Shelf-life	The shelf-life of the product at room temperatures (25°C) is given in years if it is more than two years, and in months if it is less than two years. The appropriate temperature specifications must be given.
1.9 Density	Indicate the density of the liquids.
1.10 Bulk density	Indicate the density of solids after compression.
1.11 Flammability	Specify if the product is flammable
1.12 Flash point	To determine flammable hazards.
1.13 Explosivity	
1.14 Compatibility with other pest control products	Indicate types of pest control products which the product is or is not compatible with. Give evidence.
1.15 pH range	State the effect of pH on stability and effectiveness.
1.16 pH of 1% aqueous dilution	Relevant to products to be diluted in water.
1.17 Oxidizing properties	Indicate materials that can be damaged by oxidizing properties of the formulation.
1.18 Corrosiveness	Specify effect on containers, equipment, skin etc.
1.19 Water content	Indicate the maximum water content when it has an influence on the quality.
1.20 Wettability	The wettability has to be indicated for solid formulations used in dilution (wettable powders, powder soluble in water and granules soluble in water).
1.21 Solubility in water	Specify
1.22 Persistent foaming	State the extent to which foaming occurs for formulations diluted in water.
1.23 Particle size	Specify
1.24 Suspensibility / emulsifiability	Specify
1.25 Emulsion stability	
1.26 Volatility	
1.27 Viscosity	For formulations to be used at very low volume, it is necessary to know the viscosity.

1.28 Wet sieve test	
1.29 Dry sieve test	
1.30 Method of Analysis	
1.31 Detailed composition supported by analytical evidence from certified laboratory	Content of the active ingredient(s) and their sources – the minimum and maximum a.i. content. (Documentary proof is required).
1.32 Other properties (where applicable)	FAO specifications etc.

**2. TOXICOLOGY**

The dossier must contain a detailed Material Safety Data Sheet(MSDS). 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.

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

**WHO-Classification Scheme**

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

**2.8 Other studies**

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

**3. EMERGENCY MEASURES IN CASES OF ACCIDENTAL EXPOSURE OR POISONING**

Self explanatory. List relevant information of the form and refer to relevant section in MSDS in section 3 of dossier.

**4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE**

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

**5. EFFICACY DATA**

Applicant is expected to undertake efficacy trials as follows:

- i) Where the source of the a.i. but not the formulation is identical or has been proven to be equivalent to that of a registered product, the applicant can undertake one season trial for at least 3-4 crops, in three (3) different sites per crop (for registered uses on the original molecule).
- ii) Where the source of the a.i. is not identical or equivalent to a registered product has not been proved then the applicant shall undertake a three season efficacy trial
- iii) For all new uses, three (3) season efficacy trials are required.

REQUIREMENTS:	REMARKS:
5.1 Crop/livestock/public health	The common name of the crop on which the product

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

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

## **6. MINIMUM LABEL REQUIREMENTS**

Specify the warnings, use restrictions and safety precautions which must be present on the label in all countries.

The proposed label must be included in the dossier and should contain the specified warnings, use restrictions and safety precautions as well as meet PCPB label requirements, recommendations etc. The PCPB label requirements will be provided separately.

### **LIST OF ABBREVIATIONS**

a.i.	Active Ingredient
ADI	Acceptable Daily Intake
BCF	Bio Concentration Factor
CIPAC	Collaborative International Pesticides Analytical Council Limited
CLI	CropLife International
DT <sub>50</sub>	Time it takes for 50% of the parent compound to disappear from soil or water by transformation (half life).
EC	Emulsifiable Concentrate
EC <sub>50</sub>	Median Effective Concentrate
FAO	Food and Agriculture Organization of the united nations
g/Kg	Grams per Kilogram
g/L	Grams per Litre
GCPF	Global Crop Protection Federation
GLP	Good Laboratory practice
ISO	International Standards Organisation

IUPAC	International Union of Pure and Applied Chemistry.
LC <sub>50</sub>	Median Lethal Concentrate
LD <sub>50</sub>	Median Lethal Dose
µg	Microgram
mg/L	Milligrams per litre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NOEL	Non Observable Effective Level
°C	Degrees Centigrade
PCPB	Pest Control Products Board
PHI	Pre Harvest Interval
SEARCH	Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration.
WHO	World Health Organization
WP	Wettable Powder