FORM A

REPUBLIC OF KENYA
PEST CONTROL PRODUCTS ACT, CAP 346, 1982.

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT

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
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 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)	
1.2 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: (eg. Insecticide, herbicide etc.)	
2.3 Intended use: (Veterinary, 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 no, give reasons		
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ 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 mammalian toxicological studies: eg. livestock, 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).
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 A, 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.		
1.4 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, IMR, MS		
2.25 Reactivity towards container material		

3. TOXICOLOGY

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 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. 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		
7. RESIDUES		
7.1 Major metabolites		
7.2 Metabolism		
7.3 Behaviour of residues		
7.4 Adsorption		
7.5 MRL codex		
7.6 MRL crops		
7.7 Method of residue analysis		
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 A, 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 A.

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 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 Crop/area of use		
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 Phytotoxicity		
5.8 Contraindications		
6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).		
7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medium 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.		

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.

ACTIVE INGREDIENT (TECHNICAL GRADE)

1. DESIGNATION

REQUIREMENTS:	**REMARKS:**
1. **DESIGNATION/IDENTITY OF a.i.**	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.	
1.5 Methods of manufacture(synthesis pathways)	
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	
1.11 CAS Number	

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^{o}C	
2.5 Vapour pressure at 20/25^{o}C	
2.6 Volatility	
2.7 Hydrolysis DT_{50} ….. Days …… ^{0}C pH	Give the DT_{50} of the active ingredient, with mention of temperature and pH parameters employed during the determination.
2.8 Photolysis	Give the DT_{50} of the active ingredient (in days).
2.9 Solubility in water ……^{0}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 ^{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, identityof breakdown products	

REQUIREMENTS:	**REMARKS:**
2.19 Thermal stabilty, 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	

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.

REQUIREMENTS:	**REMARKS:**
ADI	Acceptable Daily Intake in mg product / kg body weight.
NOEL	Non observable effect level (expressed in mg product / kg weight on animal)
Short term toxicity	
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 Eye irritation (rabbit)	
3.2 Skin sensitisation (guinea pig)	
3.3 Reproduction (specify species)	
3.4 Subchronic toxicity 90 day NOEL mg/kg/day	
3.5 Chronic toxicity NOEL mg./kg/day	
3.6 Carcinogenicity (life time) NOEL mg/kg/day	
3.7 Neurotoxicity NOEL mg/kg/day	
3.8 Teratogenicity NOEL mg/kg/day	
3.9 Mutagenicity /Genotoxicity	
3.10 Metabolism (rat)	
3.11 Other studies	Provide further information relevant to the toxicity profile of the product e.g. Toxicity of major metabolites, reaction or breakdown products of the pest control products formed in/or on treated plant/crop etc, which are likely to be consumed – in cases where different from those identified in animal studies. Toxic effects on livestock, poultry, pests etc. should be given.

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.

REQUIREMENTS:	**REMARKS:**	
4.1 Birds (2 species)	LD_{50} mg/kg	Provide details of at least one land and one water bird, LD_{50} in mg product/kg bird weight and the NOEL. Furthermore provide information on the effect on reproduction.
	NOEL	
	LD_{50}mg/kg	
	NOEL	
	Reproduction	
4.2 Fish (2 species)	LD_{50} mg/kg	Provide details on at least two species studied, LC_{50} (in mg of product / litre of water) and the NOEL. Furthermore provide information on the effect on reproduction. Indicate the bioconcentration factor (BCF) on the active ingredient in tissues.
	NOEL	
	LD_{50} mg/kg	
	Reproduction	
	BCF	

REQUIREMENTS:		REMARKS
4.3 Daphnia	LC_{50} mg/l	Specify and provide details on other organisms according to the information requested on the form.
	NOEL	
4.4 Algae	LC_{50} mg/l	
	NOEL	
4.5 Bees	LD_{50} µg/bee	
	NOEL	
4.6 Earthworms	LC_{50} mg/kg	
4.7 Soil micro-organisms		

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.

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

7. RESIDUES

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

REQUIREMENTS:	**REMARKS:**
7.1 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.
7.2 Metabolism	Describe the principle of metabolization of the active ingredient in the plant and the degradation products formed.
7.3 Behaviour of residues	Indicate the action and the persistence of the metabolites in the plant and animals.
7.4 Crop	Provide either an executive summary or individual summaries of studies conducted by a GLP certified laboratory or as directed by Secretary, PCPB.
7.5 MRL codex	MRL's (if available) When available state for each crop or vegetable product, the Maximum residue Limit (MRL) recommended by the Codex Alimentarius Commission, two effective MRL's in two different countries and the MRL proposed in the country of application. If the proposed crop is to be exported provide detailed information in the dossier on MRL or import tolerances in the countries exported to.
7.6 MRL of country of origin	
7.7 Proposed MRL	
7.8 Proposed PHI	
7.9 Method of residue analysis	Provide a copy in the dossier for countries requiring it.

8. OTHER SPECIFIC REQUIREMENTS

REQUIREMENTS:	**REMARKS:**
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.

REQUIREMENTS:	REMARKS:
1.1 Physical state / formulation type	Solid, liquid etc.
1.2 Colour	
1.3 Odour	
1.4 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.
1.5 Shelf-life	The shelf-life of the product at room temperatures (30°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.
1.6 Density	Indicate the density of the liquids.
1.7 Bulk density	Indicate the density of solids after compression.
1.8 Flammability	Specify if the product is flammable
1.9 Flash point	To determine flammable hazards.
1.10 Compatibility with other pest control products	Indicate types of pest control products which the product is or is not compatible with. Give evidence.
1.11 pH range	State the effect of pH on stability and effectiveness.
1.12 pH of 1% aqueous dilution	Relevant to products to be diluted in water.
1.13 Oxidizing properties	Indicate materials that can be damaged by oxidizing properties of the formulation.
1.14 Corrosiveness	Specify effect on containers, equipment, skin etc.
1.15 Water content	Indicate the maximum water content when it has an influence on the quality.
1.16 Wettability	The wettability has to be indicated for solid formulations used in dilution (wettable powders, powder soluble in water and granules soluble in water).
1.17 Solubility in water	Specify
1.18 Persistent foaming	State the extent to which foaming occurs for formulations diluted in water.
1.19 Particle size	Specify
1.20 Wet sieve test	
1.21 Dry sieve test	
1.22 Suspensibility / emulsifiability	Specify
1.23 Emulsion stability	
1.24 Volatility	
1.25 Viscosity	For formulations to be used at very low volume, it is necessary to know the viscosity.
1.26 Other properties (where applicable)	FAO specifications etc.
1.27 Method of Analysis	

2. TOXICOLOGY

The dossier must contain a detailed Material Safety Data Sheet(MSDS). Furthermore an executive summary discussing all aspects mentioned under section 2 must be included, or the summaries from each individual toxicity study under 2.1-2.6.

Other studies

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

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

WHO-Classification Scheme

Class	LD_{50} 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

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

REQUIREMENTS:	**REMARKS:**
5.1 Crop/area of use	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 ABREVIATIONS

a.i.	Active Ingredient
ADI	Acceptable Daily Intake
BCF	Bio Concentration Factor
CIPAC	Collaborative International Pesticides Analytical Council Limited.
CLI	CropLife International
DT_{50}	Time it takes for 50% of the parent compound to disappear from soil or water by transformation (half life).
EC	Emulsifiable Concentrate
EC_{50}	Median Effective Concentrate
FAO	Food and Agriculture Organization of the united nations
g/kg	Grams per Kilogram
g/*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_{50}	Median Lethal Concentrate
LD_{50}	Median Lethal Dose
μg	Microgram
mg/l	Milligrams per litre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NOEL	Non Observable Effective Level
^{o}C	Degrees Centigrade
PCPB	Pest Control Products Board
PHI	Pre Harvest Interval
SEARCH	Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration.
WHO	World Health Organization
WP	Wettable Powder