

FORM A5



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.

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 laboratory standard of its active ingredient;
 - c) 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.

TRADE NAME.....

PURPOSE OF APPLICATION (tick as appropriate)

a. A pest control product which is an adjuvant	<input type="checkbox"/>
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	<input type="checkbox"/>
e. Other (Explain)	
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f. Will the product be marketed under own label? Yes <input type="checkbox"/> No <input type="checkbox"/>
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:	

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: (Veterinary, public health, industrial, agriculture, forestry, etc.			
3.4 Target use e.g product and crop/animal			
3.5 Method, dosage rates and frequency of application:			
3.6 Type of formulation: (e.g. EC, WP, etc.)		CropLife International (CLI) [*] Code (if available)	

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

3.7a) Is the product registered in country of manufacture?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If no, give reasons	
b) Is the product registered in the country of formulation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If no, give reasons	
3.8 Registration in SEARCH ^{**} country/ies: (names)		
3.9 Proof of existing registration in other country(ies)		
3.10 Customs Tariff Code: (Brussels Tarrif Nomenclature)		

4. SPRAY ADJUVANT FORMULA (attach confidential formula)			
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

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

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 <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					

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):	
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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	<p style="text-align: center;">FOR OFFICIAL USE</p> <p>Remarks</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>Signed: Date:</p>

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 A5.

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/livestock/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		
5.8 Provide Efficacy data from similar climatic zones		
5.9 Phytotoxicity		

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

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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		
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GUIDELINE: SPRAY ADJUVANT DOSSIER

1. PHYSICAL AND CHEMICAL PROPERTIES OF THE SPRAY ADJUVANT

Clearly state methods used to determine properties under the appropriate section of the dossier. Collaborative International Pesticides Analytical Council Limited (CIPAC) methods are recommended.

REQUIREMENTS:	REMARKS:
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 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 CAS nomenclature. Their structure or structural formula should be provided. Where the information provided does not fully identify a co-formulant, an appropriate specification must 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 Surface tension	For formulation that are surfactants
1.29 Adhesion	For formulation that are stickers
1.30 Method of Analysis	
1.31 Detailed composition supported by analytical evidence from certified laboratory	Provide content of the spray adjuvant and their sources. (see spray adjuvant confidential formula form below) Documentary proof is required.
1.32 Other properties (where applicable)	FAO specifications etc.

SPRAY ADJUVANT CONFIDENTIAL FORMULA

Trade Name:

Manufacturer:

Registrant

i. Principal functioning agent

Common chemical name and CAS number	Chemical name as listed in IUPAC	Spray adjuvant function(s) performed	Nominal percentage (%)
Total percentage of principal functioning agents:			

ii. Constituents ineffective as spray adjuvant

Common chemical name and CAS number	Chemical name as listed in IUPAC	Spray adjuvant function(s) performed	Nominal percentage (%)
Total percentage of constituents ineffective as spray adjuvant:			

Total percentage of all ingredients (i&ii) (must be equal to 100%):

Name:

Title:

Signature:

Date:

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.

REQUIREMENTS:	REMARKS:
2.1 Acute oral LD ₅₀ mg/Kg rat/rabbit	Provide detailed studies and any other relevant toxicology or ecotoxicological studies conducted on the formulated product.
2.2 Acute dermal LD ₅₀ mg/Kg (rat)	
2.3 Inhalation LC ₅₀ mg/L 4hour (rat)	
2.4 Skin irritation (rabbit)	
2.5 Eye irritation (rabbit)	
2.6 Skin sensitisation (guinea pig)	
2.7 WHO classification	See table below
2.8 Other studies	Provide detailed studies

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 Product and Crop/livestock/public health	The Pest control product and crop/animal combination must be clearly specified. When the product is not aimed at a food crop, indicate the area of use, e.g. . non-crop area, animals, aquatic systems

5.2 Spray adjuvant function	Specify the mode of action of the product on its target, and indicate the enhancement or modification expected on the pest control product.
5.3 Adjuvant rate	The rate of application must be indicated using the recommended label rate. Also indicate the pesticide rates using the recommended label rate. Attach letter of authority from the registrant of the pest control product.
5.4 Spray carrier	Volume of spray carrier (water) and conditions eg pH, hardness should be reported.
5.5 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.
5.6 Directions for use	Indicate the recommended directions for use.
5.7 Residue data and pre-harvest interval	Indicate restrictions.
5.8 Provide efficacy data from similar climatic zones	Provide information on efficacy data where tested
5.9 Phytotoxicity	Indicate crop injuries resulting from addition of the adjuvant to the pesticide. Indicate restrictions where applicable.

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.

7. BEHAVIOUR IN ENVIRONMENT

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

REQUIREMENTS:	REMARKS:
7.1 Behaviour, ways of degradation, degradation products in soil:	Indicate the degradation path of the active ingredient in the soil and the degradation products formed.
7.1.1 Major metabolites	Specify the major metabolites in the soil and their behaviour.
7.1.2 DT ₅₀ (days)	Specify the half-life of the active ingredient in various types of soils.
7.1.3 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.
7.1.4 Adsorption	Indicate the degree of adsorption of the active ingredient in the soil.
7.1.5 Mobility of metabolites	Indicate the degree of mobility of the metabolites in the soil.

7.2 Behaviour, ways of degradation, degradation products in water:	Describe ways and speed of degradation of the active ingredient in water.
7.2.1 Major Metabolites	Specify the major break down products formed and their adsorption/desorption on sediments.
7.2.2 DT ₅₀ (days)	Specify the half-life of the active ingredient in water
7.2.3 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.
7.2.4 Ground water	
7.3 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).

8. RESIDUES

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

REQUIREMENTS:	REMARKS:
8.1 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.
8.2 Metabolism	Describe the principle of metabolization of the active ingredient in the plant and the degradation products formed.
8.3 Behaviour of residues	Indicate the action and the persistence of the metabolites in the plant and animals.
8.4 MRL codex or other certified sources	<u>MRL's (if available)</u> 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.
8.5 Method of residue analysis	Provide a copy in the dossier.
8.6 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.
8.7 Proposed pre-harvest intervals/ withholding periods in cases on post-harvest use.	
8.8 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products.	

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

9. MODE OF ACTION

Must be explained in full.

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 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 Organization
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
°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