

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

FORMULATION DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES

YP NO. (For Internal Use) :
 PRODUCT NAME :
 COMPANY NAME :

The following information requirements are subjected to Part E: Chapter I. Data Requirements Details under the Pesticides (Registration) Rules 2005.

	Technical Material (TC)/ Technical Concentrate (TK)	Formulation	
PART A: Summary Information for Technical Grade of Active Ingredient (TGAI)	INDUSTRY/MANUFACTURING	AGRICULTURE/ PUBLIC HEALTH/ VETERINARY/ FISHERY <i>Not require fill PART A if TGAI already registered with Pesticides Board (Provide the copy of registration certificate)</i>	HOUSEHOLD <i>Not require fill PART A if TGAI already registered with Pesticides Board (Provide the copy of registration certificate)</i>
1.Source Manufacturer and Address
2.Active Ingredient (Common Name & percent % w/w)	i)..... ii)..... iii).....	i)..... ii)..... iii).....	i)..... ii)..... iii).....
3.CAS Number	i)..... ii)..... iii).....	i)..... ii)..... iii).....	i)..... ii)..... iii).....
4.Impurities Ingredient (max limit)	i)..... ii)..... iii)..... iv)..... v)..... vi)..... <i>Attach lists of composition if there is not enough space</i>	i)..... ii)..... iii)..... iv)..... v)..... vi)..... <i>Attach lists of composition if there is not enough space</i>	i)..... ii)..... iii)..... iv)..... v)..... vi)..... <i>Attach lists of composition if there is not enough space</i>
REMARKS :			

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	Technical Material (TC)/ Technical Concentrate (TK)	Formulation	
5.Specification Reference (Year, Publication) e.g. FAO, WHO etc
6.GLP Study on Five Batch Analysis Including Impurities Profile Lab Name: Date Report: Study No.: Sponsor: Batch No.: GLP Certificate: YES/NO YES/NO YES/NO
7.Physical Chemical Appearance : Melting/Boiling Point: S.G/Density: Solubility: pH: pKa:
8.GLP/ISO 17025 Study on Storage Stability Test Lab Name: Date Report: Study No.: Sponsor: Batch No.: Temperature: Time Duration: GLP/ISO 17025 Certificate :	<i>Not require if Technical Material (TC)</i> YES/NO YES/NO YES/NO

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PART B: Summary Information for Formulated Product		AGRICULTURE/ PUBLIC HEALTH/ VETERINARY/ FISHERY	HOUSEHOLD
1.Active Ingredient (Common Name & percent % w/w or mg/mat or I.U/mg)		i)..... ii)..... iii).....	i)..... ii)..... iii).....
2.Inert Ingredients (percent %w/w)		i)..... ii)..... iii)..... iv)..... v)..... vi).....	i)..... ii)..... iii)..... iv)..... v)..... vi).....
3.Type of Formulation	
4.Specification Reference (Year, Publication) e.g. FAO,WHO etc	
5.Specification Properties Refer Appendix I or II or III.		<p align="center"><i>Refer Appendix I</i></p> <p>i) Density properties: Density:</p> <p>ii) Surface Properties: Wettability: Persistent Foam:</p> <p>iii) Volatilization Properties Volatility:</p>	<p align="center"><i>Refer Appendix II (MC, MV, LV, AE)</i></p> <p>Weight of Coils: Burning Time: Strength of Coil: Size of Mat: Evaporation Rate: Internal Pressure: Discharge Rate: pH Range : Netting Mesh Size: Bursting Strength:</p>

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		iv) Particulate/Fragmentation Properties: Wet Sieve Test: Dry Sieve Test: Dustiness: v) Dispersion Properties: Dispersibility: Suspensibility: Dispersion Stability: Emulsion Stability: vi) Flow Properties: Flowability: Pourability: Viscosity:	<i>Refer Appendix III</i> pH Range: Density/S.G: Odour: Appearance: Evaporation Rate: Viscosity: Block Size: Net Weight: Dry Sieve Test:
6.GLP/ISO 17025 Study on Storage Stability Test Lab Name: Date Report: Study No.: Sponsor: Batch No.: Temperature: Time Duration: GLP/ISO 17025 Certificate:	 YES/NO YES/NO
7.Five Batch on Quality Control Lab Name: Date Report: Study No.: Sponsor: Batch No.:	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Appendix I: Specification guidelines for pesticide formulated product (AGRICULTURE/PUBLIC HEALTH).

Formulation	Specification Properties*													
	Density Properties	Surface Properties		Volatilization Properties	Particulate/ Fragmentation Properties			Dispersion Properties				Flow Properties		
	Density	Wettability	Persistent Foam	Volatility	Wet Sieve Test	Dry Sieve Test	Dustiness	Dispersibility	Suspensibility	Dispersion Stability	Emulsion Stability	Flowability	Pourability	Viscosity
Dustable Powders (DP)						•								
Granules (GR)	•						•							
Wettable Powders (WP)		•	•		•				•					
Water Dispersible Granules (WG)		•	•		•		•	•	•			•		
Water Dispersible Tablets (WT)			•		•				•					
Water Soluble Powders (SP)		•	•											
Water Soluble Granules (SG)			•				•					•		
Soluble Concentrates (SL)			•											
Ultra Low Volume Liquids (UL)														•
Emulsifiable Concentrates (EC)			•								•			
Dispersible Concentrates (DC)			•		•					•				
Emulsion, Oil In Water (EW)			•								•		•	
Micro-Emulsions (ME)			•								•			
Suspension Concentrates (SC)			•		•				•	•			•	

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Formulation	Specification Properties*													
	Density Properties	Surface Properties		Volatilization Properties	Particulate/ Fragmentation Properties			Dispersion Properties				Flow Properties		
	Density	Wettability	Persistent Foam	Volatility	Wet Sieve Test	Dry Sieve Test	Dustiness	Dispersi-bility	Suspensi-bility	Dispersion Stability	Emulsion Stability	Flowability	Pourability	Viscosity
Capsule Suspensions (CS)			•		•				•	•			•	
Suspo-Emulsions (SE)			•		•					•			•	
Mixed Formulations of CS and SC (ZC)			•		•				•	•			•	

Appendix II: Specification guidelines for pesticide formulated product (HOUSEHOLD).

Formulation	Specification Properties*												
	Average Weight	Burning Time	Strength of Coil	Separation of Twin Coils	Size of Mat	Evaporation Rate	Cartridge/ Bottle	Wick	Minimum Effective Period	Net Content	Internal Pressure	Discharge Rate	pH Range
Mosquito Coils (MC)	•	•	•	•									
Vaporizing Mats (MV)					•	•							
Liquid Vaporizers (LV)						•	•	•	•				
Aerosol Dispensers (AE)										•	•	•	•

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Appendix III: Specification guidelines for pesticide formulated product (HOUSEHOLD).

Formulation	Specification Properties*									
	pH Range	Density/ Specific gravity	Odour	Colour	Appearance	Evaporation Rate	Viscosity	Block Size	Net Weight	Dry Sieve Test
Block Bait (BB)	•	•	•	•				•		
Paint	•	•	•	•		•				
Lotion	•		•	•	•				•	
Liquid (AL)	•	•	•	•	•		•			
Powder (AP)	•	•		•						•
Bait Concentrate (CB)		•	•	•	•					
Ant Bait (RB)		•	•	•	•		•			
Wipes			•						•	
Gel		•	•	•	•		•		•	
Spot-on (SA)	•		•	•					•	

Note (*): Registrant must refer to Manual on development and use of FAO and WHO specifications for pesticides (First edition) if formulation of the product is not listed in Appendix I, II and III.

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3.1.5 Eyes irritation study (in rabbits)	Study No. : Sponsor : Guideline : GLP : Result :
3.1.6 Dermal/Skin sensitisation study (in guinea pig)	Study No. : Sponsor : Guideline : GLP : Result :
3.1.7 Acute delayed neurotoxicity in hens (for organophosphates and carbamates)	Study No. : Sponsor : Guideline : GLP : Result :
Recommended Classification :	

REMARK

1. Required data toxicity on technical for technical registration and data toxicity on formulation for formulated registration.
2. For household and preservative product if no formulated toxicity report available upon registration submission, kindly submit:
 - a. Letter of Authorization to refer TGAi toxicology from A.I supplier with registered LRMP No.
 - b. Summary of report studies of TGAi
 - c. Calculation for estimated LD₅₀ or acute toxicity estimate (ATE)
 - d. Additional 4 pack studies of TGAi

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

	GLP : Result :
3.1.6 Dermal/Skin sensitisation study (in guinea pig)	Study No. : Sponsor : Guideline : GLP : Result :
3.1.7 Acute delayed neurotoxicity in hens (for organophosphates and carbamates)	Study No. : Sponsor : Guideline : GLP : Result :
Recommended Classification :	
3.2 Sub-acute Toxicological Data	
3.2.1 Repeated dose 21 or 28 days dermal toxicity study (in rats)	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :
3.2.2 Repeated dose 28 days oral delayed neurotoxicity in hens (organophosphates and carbamates if triggered by findings of acute delayed neurotoxicity)	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :
3.2.3 Sub-acute 90 days dietary feeding study (in rats)	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :
3.3 Chronic Toxicological Data	
3.3.1 Chronic dietary feeding study (24 months in rats, 18 months in mouse and 1 year in dogs)	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

3.3.2 Carcinogenicity study (not less than 24 months for rats and 18 months for mouse. This study can be combined with chronic feeding study, if appropriate)	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :
3.4 Supplemental Toxicological Data	
3.4.1 Developmental study (2 species, one rodent and one non-rodent)	<div> <u>Rodent</u> Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL : </div> <div> <u>Non-Rodent</u> Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL : </div>
3.4.2 Reproductive study (2 generations of rodents and one litter).	Study No. : Sponsor : Guideline : GLP : NOAEL : LOAEL : NOEL :
3.4.3 Genotoxicity study (at least in 3 battery of tests to detect gene mutation, chromosomal aberration and genotoxic effects).	<div> <u>Gene mutation</u> Study No. : Sponsor : Guideline : GLP : Result : </div> <div> <u>Chromosomal aberration</u> Study No. : Sponsor : Guideline : GLP : Result : </div>

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

	<u>Micronucleus test</u> Study No. : Sponsor : Guideline : GLP : Result :
3.4.4 Metabolic study (at least one species)	Study No. : Sponsor : Guideline : GLP : Result :
3.5 Human toxicology data (such as industrial exposure data, accidental data or volunteer data)	Study No. : Sponsor : Guideline : GLP : Result :
3.6 Toxicological information of every ingredient, synergist, and major or important impurity of the pesticides.	Study No. : Sponsor : Guideline : GLP : Result :

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Chapter 5: Fate and Behaviors in The Environment	
5.1 Definition of the residue relevant to the environment	
5.2 Degradation and dissipation studies	
i. Degradation Studies (Laboratory) <ul style="list-style-type: none"> a. Hydrolysis b. Photolysis <ul style="list-style-type: none"> ◆ Water ◆ Soil 	Study No. : Sponsor : Guideline : GLP : Result : Study No. : Sponsor : Guideline : GLP : Result : Study No. : Sponsor : Guideline : GLP : Result :
ii. Dissipation Studies (Field) <ul style="list-style-type: none"> a. Soil b. Aquatic (<i>Sediment</i>) 	Study No. : Sponsor : Guideline : GLP : Result : Study No. : Sponsor : Guideline : GLP : Result :

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<p>5.3 Metabolism Studies (Laboratory)</p> <ul style="list-style-type: none"> i. Aerobic <ul style="list-style-type: none"> a. Soil b. Aquatic <i>(Water Sediment)</i> ii. Anaerobic <ul style="list-style-type: none"> a. Soil <i>(Required in flooded soil)</i> 	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>
<p>5.4 Mobility studies</p> <ul style="list-style-type: none"> i. Leaching and adsorption or desorption in soil 	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>
<ul style="list-style-type: none"> ii. Volatility <ul style="list-style-type: none"> a. Laboratory 	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>
<ul style="list-style-type: none"> <ul style="list-style-type: none"> b. Field 	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>
<p>5.5 Fate and behavior in air</p>	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>
<p>5.6 Bioaccumulation study in fish <i>(Preferred fish: Bluegill sunfish and Channel catfish)</i></p>	<div>Study No.</div> <div>:</div> <div>Sponsor</div> <div>:</div> <div>Guideline</div> <div>:</div> <div>GLP</div> <div>:</div> <div>Result</div> <div>:</div>

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Chapter 6: Effect on Non-Target Species	
6.1 Effects on terrestrial vertebrates (including acute oral toxicity to avian species e.g. pigeon, quail, pheasant or duck)	Study No. : Sponsor : Guideline : GLP : LD ₅₀ :
6.2 Effects on aquatic species	
i. Acute toxicity on one suitable fish species	Study No. : Sponsor : Guideline : GLP : LC ₅₀ (96 hr) :
ii. Acute toxicity on other aquatic organisms (e.g. <i>Daphnia</i> and <i>Crustacea</i>)	Study No. : Sponsor : Guideline : GLP : LC ₅₀ (48 hr) :
6.3 Effects on bees and other arthropod species (including acute oral and contact toxicity on honey bees)	<div> <u>Acute oral</u> Study No. : Sponsor : Guideline : GLP : LD₅₀ : </div> <div> <u>Contact toxicity</u> Study No. : Sponsor : Guideline : GLP : LD₅₀ : </div>
6.4 Effects on earthworms and other soil macro-organisms (including acute toxicity on earthworms)	Study No. : Sponsor : Guideline : GLP : LC ₅₀ : NOEC :
6.5 Effects on other non-target organisms (flora and fauna)	<div> <u>Flora</u> Study No. : Sponsor : Guideline : GLP : Result : </div> <div> <u>Fauna</u> Study No. : Sponsor : Guideline : GLP : Result : </div>

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REMARK

1. Required data toxicity on technical for technical registration and data toxicity on formulation for formulated registration.
2. For household and preservative product if no formulated toxicity report available upon registration submission, kindly submit:
 - a. Letter of Authorization to refer TGAI toxicology from A.I supplier with registered LRMP No.
 - b. Summary of report studies of TGAI
 - c. Calculation for estimated LD₅₀ or acute toxicity estimate (ATE)
3. For items 3.5 and 3.6, if available and particularly needed the poisoning data and information on antidotes.

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

EFFICACY DATA REQUIREMENTS FOR REGISTRATION OF AGRICULTURE PESTICIDE

GENERAL	
YP No.: (For Internal Use)	Product Name:
Company Name:	
Active Ingredient:	Formulation:
1).....%	Pesticide Type:
2).....%	
3) %	
Chemical Group:	MOA Code:
1)	1)
2)	2)
3)	3)
Mode Of Action (related to the preamble):	
1)	
2)	
3)	
EFFICACY DATA	
(Please fill in an another form if more than one (1) crop is recommended)	
Efficacy Trial Topic:	
Efficacy Trial Location:	Year of Efficacy Trial:
Crop:	
Pest Scientific Name:	Pest Common Name:
1)	1)
2)	2)
3)	3)
4)	4)
5)	5)
Phytotoxic effect on crop: Yes / No	Effects on natural enemies: Yes / No
Potential occurrence to resistance: Yes / No	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Pesticide Rate	
i. a.i./ Ha:	iii. For 1 Ha:
ii. 10 L Water:	iv. Volume:
Application Method:	Application Tools:
Nozzle Type:	Nozzle Size:
Days of Interval:	Maximum Seasonal Application:
Secondary Poisoning (Barn Owl): (for rodenticide only)	
Additional Information: a) Crop Age: (for oil palm/ rubber) b) Crop Canopy (</ >30%):	
Pesticide Rate Calculation Method	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

EFFICACY DATA REQUIREMENTS FOR REGISTRATION OF HOUSEHOLD PESTICIDE

GENERAL				
YP No.: (For Internal Use)		Product Name:		
Company Name:				
Active Ingredient:		Formulation:		
1).....%		Pesticide Type:		
2).....%		Usage Type: FIK/ CIK/ Rat/ Repellant/ Residual*		
3) %		*Choose one		
Chemical Group:				
1) 2).....				
3)				
EFFICACY DATA				
(Please fill in an another form if more than one (1) area/ location is recommended)				
Protocol/ Standard:				
Efficacy Trial Topic :				
Efficacy Trial Location:		Year of Efficacy Trial:		
Discharge Rate: (for aerosol only)		Burning Time: (for coil only)		
Vaporizing Rate: (for mat/ net/ paper/ liquid)				
Rate: (for bait/ granule)				
Infested Area/ Location: (as recommended on label)				
Pest Scientific Name:	Pest Common Name:	KT ₅₀ :	KT ₉₅ : (if applicable)	% Mortality: (if applicable)
1)	1)	1)	1)	1)
2)	2)	2)	2)	2)
3)	3)	3)	3)	3)
4)	4)	4)	4)	4)
5)	5)	5)	5)	5)
Room Size:		Protection Period:		
Application Method:				
Pesticide Rate Calculation Method (if applicable)				

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

**EFFICACY DATA REQUIREMENTS FOR REGISTRATION OF PRESERVATIVES/ DISINFECTANT/
PAINT/ VETERINAR PESTICIDE**

GENERAL	
YP No.: (For Internal Use)	Product Name:
Company Name:	
Active Ingredient:	Formulation:
1).....%	Pesticide Type:
2).....%	
3) %	
Chemical Group:	MOA Code:
1)	1)
2)	2)
3)	3)
Mode Of Action (related to the preamble):	
1)	
2)	
3).....	
EFFICACY DATA	
(Please fill in an another form if more than one (1) material/ fluid/ host is recommended)	
Efficacy Trial Topic:	
Efficacy Trial Location:	Year of Efficacy Trial:
Material/ Fluid/ Host:	
Pest Scientific Name:	Pest Common Name:
1)	1)
2)	2)
3)	3)
4)	4)
5)	5)

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Pesticide Rate:	Mixing Rate: (for Preservatives only)
Application Method:	
Duration of Protection:	
Pesticide Rate Calculation Method	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

**EFFICACY DATA REQUIREMENTS FOR REGISTRATION OF PEST CONTROL OPERATOR (PCO) &
PUBLIC HEALTH PESTICIDE**

GENERAL	
YP No.: (For Internal Use)	Product Name:
Company Name:	
Active Ingredient:	Formulation:
1).....%	Pesticide Type:
2).....%	
3) %	
Chemical Group:	MOA Code:
1)	1)
2)	2)
3)	3)
Mode Of Action (related to the preamble):	
1)	
2)	
3)	
EFFICACY DATA	
(Please fill in an another form if more than one (1) area is recommended)	
Efficacy Trial Topic:	
Efficacy Trial Location:	Year of Efficacy Trial:
Area:	
Pest Scientific Name:	Pest Common Name:
1)	1)
2)	2)
3)	3)
4)	4)
5)	5)

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Pesticide Rate	
i. a.i./ Ha:	iii. For 1 Ha:
ii. 10 L Water:	iv. Volume:
Others rate:	
Application Method:	Application Tools:
Nozzle Type:	Nozzle Size:
Days of Interval: (if applicable)	Maximum Seasonal Application: (if applicable)
Pesticide Rate Calculation Method	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

EFFICACY DATA REQUIREMENTS FOR REGISTRATION OF AGRICULTURE PESTICIDE
(GP5/2000)

GENERAL	
YP No.: (For Internal Use)	Product Name:
Company Name:	
Active Ingredient: 1).....%	Formulation:
	Pesticide Type:
Chemical Group: 1)	MOA Code: 1)
Mode Of Action (related to the preamble): 1)	
PESTICIDE RECOMMENDATION AS GP5/2000 (Please fill in an another form if more than one (1) crop is recommended)	
Crop:	
Pest Scientific Name: 1) 2) 3) 4) 5)	Pest Common Name: 1) 2) 3) 4) 5)
Pesticide Rate	
i. a.i./ Ha:	iii. For 1 Ha:
ii. 10 L Water:	iv. Volume:
Application Method:	Application Tools:
Nozzle Type:	Nozzle Size:
Days of Interval:	Maximum Seasonal Application:
Additional Information: a) Crop Age: (for oil palm/ rubber) b) Crop Canopy (</ >30%):	

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

RESIDUE DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
(FOOD CROP/VETERINAR ONLY)

*Not required to submit residue data requirement forms if no residue data submitted for the product

GENERAL	
YP No. : (For internal use)	Product Name :
Company Name :	
Active Ingredient(s) : 1) 2) 3)	
Crop recommendation (s) :	
Crop Grouping (Commodity) :	
Pest Recommendation (s) :	
Residue Definition:	i) Enforcement : ii) Dietary Assesment : iii) Metabolites :

SUMMARY OF DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

RESIDUE TRIAL DATA (Please fill in an another form if more than one (1) active ingredient and one (1) crop is recommended)			
Active Ingredient			
Crop			
Source of Pesticide Residue Data [JMPR (state year) / own data (specify the title)]			
(Please Fill in another form if more than three (3) residue study is submitted)			
Residue Study	1	2	3
Country, Year			
No. of spray			
Rate			
Label Recommended Rate (kg ai/ha) :		Label Max. No. Of Sprays :	
Pre-Harvest Interval (PHI) :		Proposed MRL (mg/kg) :	
Acceptable Daily Intake (ADI) :		Acute Reference Dose (ARfD) : (if applicable)	
MRLs in other Countries (mg/kg) (if any)			
Codex :	EU :	US:	Japan :
ASEAN :	Other :	Other :	Other :

* Use another form if more than 3 location

* Only one form for one commodity and one active ingredient (a.i)

Updated on : 25th February 2022