Application form of Requirements for Agro-pesticide Registration (organic chemical agents)

Applicant	(Stamp)		Address		
Person in charge	(Stamp)				
Tel. No.		Fax.		E-mail	
Common name			Target pests		
Application category	□ A. New active ingredients □ B. New formulation or content (includes mixture) □ C. New range of use □ D. Have been registered for 8 years (□New source technical material) □ S. Other (_____) Please fill or check the box to select the item				
Has applied for or registered for: Product Intended use License No.					

1. Product Informaton：

1.1 Identity

1.1.1 Formulation and concentration: _____

1.1.2 Brand name (product code): Chinese name: _____ English name: _____

1.2 Active ingredients: (If more than one, please use additional fields)

1.2.1 Common Name: (Chinese) _____

(English) _____

1.2.2 Chemical name: (IUPAC) _____

(CA) _____

1.2.4 Molecular formula _____

1.2.5 Molecular weight _____

1.2.6 CAS RN _____

1.2.7 CIPAC #： _____

1.2.8 RAC code _____

1.2.9 Classification _____

1.2.10 Mode of action

1.2.3 Structure formula：

2. The composition and physical-chemical properties of the technical grade agro-pesticide (If more than one, please use additional fields)

2.1 Nominal content (or certified limited)：_____

※The value should be based on the five batch analysis data

2.2 Manufacturer:

2.2.1 Name _____

2.2.2 Address _____

2.2.3 Country _____

2.2.4 Source of authority _____

2.3 Registration Company _____

2.4 License No. _____

2.5 Composition

2.5.1 Data information Report title: _____

Report No. _____ Report date：_____

Test facility: _____

GLP registered org.: □ Yes, Registered No., Country, Expiration date _____

□ No

2.5.2 The composition of technical material (TC):

	No.	Name or code	Chemical name	CAS No	Content (%) Upper limit	Lower limit	Mean ±SD	Remarks
Active ingredients:	1							
	2							
Other ingredients (impurity)：	1							
	2							

2.5.3 The composition of technical concentrate (TK):

	No.	Name or code	Chemical name	CAS No	Content (%)	Remarks
Active ingredients:	1					
Other ingredients	1					

2.6 The physical-chemical properties of technical material(TC)

Test item	Result	Test material (purity / batch No.)	Condition and Method	Test facility (GLP registered status)and report No.
2.6.1 Physical state				
2.6.2 Color				
2.6.3 Odor				
2.6.4 pH values				
2.6.5 Melting point				
2.6.6 Boiling point				
2.6.7 Density,Specific gravity,Bulk density				
2.6.8 Vapor pressure				
2.6.9 Solubility				
2.6.9.1Water				
2.6.9.2 Solvent				
2.6.10 Viscosity				
2.6.11 Stability				
2.6.11.1 Heat				
2.6.11.2Metal				
2.6.11.3 Light				
2.6.12 Miscibility				

2.6.13 Flammability				
2.6.13.1 Flash point				
2.6.13.2 Flammable				
2.6.13.3 Autoignition temperature				
2.6.14 Explodability				
2.6.15 Corrosive characteristics				
2.6.16 Storage stability				
2.6.17 Partition coefficient				
2.6.18 Dissociation constant				

2.7 The physical-chemical properties of technical concentrate(TK)

Test item	Result	Test substance (purity / batch No.)	Test Methods And conditions	Test facility (GLP registered status)and report No.
2.7.1 Physical state				
2.7.2 Color				
2.7.3 Odor				
2.7.4 pH				
2.7.5 Density,Specific gravity,Bulk density				
2.7.6 Viscosity				
2.7.7 Flammability				
2.7.7.1 Flash point				
2.7.7.2 Flammable				

2.7.7.3 Autoignition temperature				
2.7.8 Explodability				
2.7.9 Corrosive characteristics				
2.7.10 Storage stability				

3. Formulated agro-pesticide composition and Physico-chemical Property

3.1 Active Ingredient content

3.2 Manufacturing

3.2.1 Name

3.2.2 Address

3.2.3 Country

3.2.4 Sources of authority

3.3 Registration Company

3.5 License Number

3.5 Compostion：

	No.	Name or code	Chemical Name	CAS No	Content (%)	Agents Function
Active ingredients	1					
Other ingredients	1					
	2					

3.6 formulated agro-pesticide for Physico-chemical Property

Test Item	Results	Substance to be Tested (Purity/Batch No.)	Testing methods and condition	Test Unit (GLP login status) and report number
3.6.1 Physical state				
3.6.2 Color				
3.6.3 Odor				
3.6.4 pH				

3.6.5 Density,Specific gravity,Bulk density				
3.6.6 Viscosity				
3.6.7 Miscibility				
3.6.8 Flammability				
3.6.8.1 Flash point				
3.6.8.2 Flammable				
3.6.8.3 Autoignition temperature				
3.6.9 Explodability				
3.6.10 Corrosive characteristics				
3.6.11 Storage stability				

4、Quality control

4.1composition analysis

	Batch NO.	Results	standard certified limits	Analysis method and condition
4.1.1 Technical grade agro-pesticide				
4.1.1.1 Active ingredients				
4.1.1.2 hazardous impurities				
4.1.1.3 Other ingredients				

4.1.2.1
Active ingredients _____

4.1.2.2
Other hazardous impurities _____

4.2 specifications of the formulated agro-pesticide formulation. _____

Specifications Item	Batch NO.	Results	standard certified limits	Analysis method and condition
Emulsion stability				
Suspensibility				
Spontaneity of dispersion				
Foaming				
wettability				
Degree of fineness				
Particle size				
Solubility				
Other(fill in name)				

5、Toxicology study

5.1 Acute toxicity tests

5..1.1 Oral toxicity

Rat	female	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)
	male	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)
Mice	female	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)
	male	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)

5.1.2 Dermal toxicity

Rabbit	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)
Other animal ()	LD_{50} _____	mg/Kg (T.C.)；	LD_{50} _____	mg/Kg (Formulated agro-pesticide)

5.1.3 Inhalation toxicity

Rat	female	LC_{50} _____	mg/L (T.C.)；	LC_{50} _____	mg/L (Formulated agro-pesticide)
	male	LC_{50} _____	mg/L (T.C.)；	LC_{50} _____	mg/L (Formulated agro-pesticide)
Other animal (____)		LC_{50} _____	mg/L (T.C.)；	LC_{50} _____	mg/L (Formulated agro-pesticide)

5.1.4 Eye irritation

T.C.：_____

Formulated agro-pesticide：_____

5.1.5 Skin irritation

T.C.：_____

Formulated agro-pesticide：_____

5.1.6 Skin Sensitization

T.C.：_____

Formulated agro-pesticide：_____

5.2 Subchronic tests (Note：NOAEL, no observed effect level)

5.2.1 90-day feeding toxicity

Rat	female	NOAEL	6.0	mg/kg/day
	male	NOAEL	10.8	mg/kg/day
Mice	female	NOAEL	120	mg/kg/day

5.1.7 Acute neurotoxicity

Hen (delayed) Yes： _____ ，dose： _____ mg/kg or No： _____

Rat Yes： _____ ，dose： _____ mg/kg or No： _____

5.2 Subchronic tests (Note：NOAEL, no observed effect level)

5.2.1 90-day feeding toxicity

Rat	female	NOAEL _____	mg/kg/day
	male	NOAEL _____	mg/kg/day
Mice	female	NOAEL _____	mg/kg/day
	male	NOAEL _____	mg/kg/day
Other animal (dog)	(female/ male)	NOAEL _____	mg/kg/day

5.2.2 Inhalation (___28 days or_✓__90 days)

Rat	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day

5.2.3 (21 days)

Rat	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day

5.2.4 Nurotoxicity (90 days)

Rat	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day

5.3 Chronic toxicity tests

5.3.1 Chronic feeding toxicity tests

Rat	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day
Mice	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day
Dog	(female)	NOAEL _____	mg/kg/day
	(male)	NOAEL _____	mg/kg/day

5.3.2 Oncogenicity tests (Note：lowest-observed-adverse-effect level, LOAEL)

Rat (female) oncogenicity NOAEL _____ mg/kg/day ；oncogenicity LOAEL _____ mg/kg/day

(male) oncogenicity NOAEL _____ mg/kg/day ；oncogenicity LOAEL _____ mg/kg/day

Mice (female) oncogenicity NOAEL _____ mg/kg/day；oncogenicity LOAEL _____ mg/kg/day

(male) oncogenicity NOAEL _____ mg/kg/day；oncogenicity LOAEL _____ mg/kg/day

Dog (female) oncogenicity NOAEL _____ mg/kg/day；oncogenicity LOAEL _____ mg/kg/day

(male) oncogenicity NOAEL _____ mg/kg/day；oncogenicity LOAEL _____ mg/kg/day

5.3.3 Reproductive toxicity

Rat/Other animal (　　) parental (systemic) NOAEL (female) ____ (male) ____ mg/kg/day

descendantal NOAEL (female) ____ (male) ____ mg/kg/day

reproductive NOAEL (female) ____ (male) ____ mg/kg/day

5.3.4 Prenatal developmental toxicity

Rat/Other animal (____) NOAEL：maternal ____mg/kg/day；fetus _____mg/kg/day

Rabbit/Other animal (____) NOAEL：maternal ____mg/kg/day；fetus _____mg/kg/day

5.4 Mutagenicity tests

5.4.1 Bacterial reverse gene mutation assay：

positive _____ dose _____；negative _____

5.4.2 *In vitro* mammalian cell assay：

positive　　dose　　；negative

5.4.3 *In vivo* cytogenetics：

positive _____ dose _____；negative _____

5.5 Metabolism studies

5.5.1 Metabolism in animal：

testing animal：

absorption rate：

organ mainly distribution and rate：

excretion route：

metabolic route ：

main metabolites：

5.5.2 Metabolism in plants：

The test crop：

Adsorption and distribution：

The metabolic pathway：

The major metabolites：

5.6 Environmental fate studies

5.6.1Hydrolysis The major metabolite：

Half-life：(Temp.___ pH____)

5.6.2 Photodegradation in water The major metabolite：

Half-life：

5.6.3 Photodegradation in soils The major metabolite：

Half-life：

5.6.4 Metabolism in soils Characteristics of soil：

The major metabolite：

>0.01ppm metabolite：

Half-life：

5.6.5 Metabolism in aquatic

Aquatic environment system：_____

Characteristics of sediment：_____

The major metabolite：_____

_____

>0.01ppm metabolite)_____

_____

Half-life：_____

5.6.6 Mobility in soil (Leaching and adsorption /desorption studies)：_____

adsorption：Koc ml/g

% in the leachate： %

5.6.7 Dissipation in soil：_____

Characteristics of soil ：S1: loam, organic matter:% ,pH

application rate： g ai/ha

Half-life: days

5.6.8 Bioaccumulation (___T.C. or ___Formulated agro-pesticide)：

Species：_____；BCF：_____

5.7 Avian and aquatic toxicity tests

5.7.1 fresh water fish ( ) or other organism( )：

LC_{50} (96hr) ，T.C._____ mg/L ；Formulated agro-pesticide_____ mg/L

5.7.2 invertebrate aquatic organism( )：

EC_{50} (48hr) ，T.C._____ mg/L ；Formulated agro-pesticide_____ mg/L

5.7.3 fish or aquatic invertebrate life cycles study (T.C. or Formulated agro-pesticide)：

species：_____；NOEC_____ mg/L ；LOEC_____ mg/L

5.7.4 avian toxicity (T.C.)：

species：_____； acute oral toxicity LD_{50}_____ mg/kg

species：_____； Feeding toxicity LC_{50}_____ ppm

5.8 Toxicity to non-target Insects (Honey bees)	(If the registered pesticide was applied indoors or other tactics may be identified as low risk concern to activity of honeybees. The data are non-required.)
5.8.1 Requirement for registering in the field condition:	
(1).Data of acute contact toxicity of Technical-Grade pesticide against honey bees (LD_{50}, μg/bee)：	(Basal requirement for new registering pesticide.)
(2) Data of acute oral toxicity of Technical Grade pesticide against honey bees (LD_{50}, μg/bee)(AOH)：	(Basal requirement for new registering pesticide.)
(3) Data of acute contact toxicity of formulated pesticide against honeybees (LD_{50}, μg/bee)(ACH)：	(Required if the target crops were the nectar or pollen plants.)
(Optional)	
(4) Reports of semi-field or field trial study of bee colony:	If the risk quotient (RQ, the ratio of ACH of formulated pesticide or AOH of technical grade pesticide to gram active ingredient per hectare) was equal to or more than 50, the data of semi-field or field trial study of bee colony is required.
(Optional)	
(5) Acute oral toxicity of formulated pesticide against larval bees (LD_{50}, μg/bee):	(If the active ingredient had other sub-lethal effects to honey bees such as side effect on the development of reproduction or growth regulator etc., data of acute oral toxicity of larval bees are required.)
(Optional)	
Acute toxicity or side effect to other beneficial insects	

5.9 Earthworm toxicity

77 LC_{50}：

5.10 Toxic to none-targeted plant

5.10.1：Families of sensitive plants

6. Efficacy trials and crop safety (phytotoxicity) trials — Brief summary of conducted year, nations or locations, dosages of test product used and replicates per treatment in trials

6. Crop _____

Targets controlled _____

7. Field of Use and Notes — Dilution rate:
Product kg or Liter per hectare:
Application stage:
Application interval:
Application number:
Notes on application:

8、Residue data：

8. Crop/variety ： ；Pest ： ；dilution rate：

Rate:g ai/ha ： ；applied at rates of g of (a.i.) in L of water：

Fraction at harves：

The result of residual experiment: trial no: □completed trial □validation trial (one trial, one table)

(DALA)*	Residues (ppm)								
	pesticide			metabolites			metabolites		
	control	Rate (low dose): g ai/ha	Rate (high dose): g ai/ha	control	Rate (low dose): g ai/ha	Rate (high dose): g ai/ha	control	Rate(low dose): g ai/ha	Rate (high dose): g ai/ha

*：Days after the last application

9、MRLs information：

Please fill the announced international MRLs and residue definition on agricultural products for applying pesticide registration, such as MRL/residue definition of one pesticide on grape)：Codex=1.0 ppm/active ingredient A + metabolite B；EU=0.5 ppm/ active ingredient A + metabolite B + metabolite C；US=2.0

ppm/ active ingredient A + metabolite B；Japan=2.0 ppm/ active ingredient A+ metabolite B；Australia=1.0 ppm/active ingredient A…。