

**APPLICATION FORM FOR REGISTRATION OF
A BIOCIDAL PRODUCT(insecticide)**

<u>Code:</u>	
<u>Application No.:</u>	
<u>Submission Date:</u>	
<u>Submission Time:</u>	
<u>Receipt Number:</u>	

This part is filled by CAPA.

This form consist of 8 pages and it is essentially required for biocidal product registration, If you find any part of this application not applicable to your product briefly mention why.

This form should be dully filled in and submitted to the Central administration of pharmaceutical affaires, 21 Abdel Aziz Al Soud – El Manial, Tel: 23648046 – fax # 23684194, together with the relevant data as prescribed in the Application requirements for Registration of biocidal Products.

Section 1 - Application Description.

A.1	Application Type:	<input checked="" type="checkbox"/> Public Health	<input type="checkbox"/> Household
A.2	Market status:	<input type="checkbox"/> Export Only	<input checked="" type="checkbox"/> Local
A.3	Type of registration:	<input type="checkbox"/> Imported (finished product)	<input type="checkbox"/> Imported (bulk)
		<input checked="" type="checkbox"/> local (formulated)	<input type="checkbox"/> Local (under license)

Company Details

	Applicant (Marketing Authorization Holder)	Manufacturer
Company Name	International Center For Marketing and Trading (ICM)	International Center For Marketing and Trading (ICM)
Address	34, Mahmoud Khiary St. Nasr City-Cairo-Egypt	Badr City Industrial
Postcode	11717	
Registration Manager	Eng, Mohamed Mostafa	Eng, Mohamed Mostafa
Telephone Number	0224054744	0224054744
Fax Number	0224054740	0224054740
Email Address	registration@icm-eg.com.eg	registration@icm-eg.com

Registration representative details:

Name : AYMAN ELSHAFIY	Telephone : 0224054744
E-mail : registration@icm-eg.com.eg	Signature and date :26 /9/2011

Section 2 - Product Information.

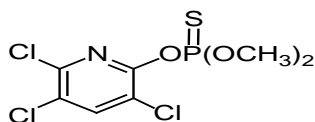
1-Pharmaceutical form : Emulsifiable Concentrate

2-Composition Details

(a)Active Substance(s)

Name of active substance (IUPAC name)	CAS/EC Number	Trade Name	Name and address of manufacturing source	Tech. purity (% w/w) or (% w/v)	Conc. % w/w	Conc in WHO
0.0-dimethyl-0-3.5.6-trichloro-2-pyridyl phosphorothioa	5598-13-0	Chloropyrifos methyl	Nanjing Essence Fine Chemical	97%	500gm/l	50%

Structural formula :-



Physical and chemical properties:

1. Physical form.	Crystalline
2. Colour & Odour:-	Colorless a slight mercaptan odor
3. Molecular weight :	322.5
4. Vapor pressure:-	N.A
5. M.P. or B.P. :-	N.A – N.A
6. Density	N.A
7. Solubility :-	In water insoluble

(b)Other components of the formulation (inactive)

Name of component (IUPAC name)	CAS/EC Number	Trade Name	Function of Components	Conc %	Notes
Glycerol monococate	61789-05-7	Lumulse	Emulsifier	10%	
Kerosene	8008-20-6	Kerosene – odorless	Solvent	40%	

Section 3 - Product/Formulation Information

- Specification of formulations :-

APPEARANCE :- (PHYSICAL FORM)		White yellow
1.	ALKALINITY OR ACIDITY :- (INCASE OF LIQUID)	N.A (ref. WHO specification)
2.	SUSPENSIBILITY: (INCASE OF SUSPENSION)	Sibility
3.	EMULSIFICATION PROPERTIES :- (INCASE OF EMULSION)	Emulsifiable Concentrate
4.	DENSITY :-	1.64 (23°C)
5.	VISCOSITY :-	N.A
6.	FLASH POINT :-	Does not flash
7. N.A	FREEZE POINT :-	182 °C
8.	WETTABILTY :- (INCASE OF POWDER)	---
9.	PARTICLE SIZE :-	N.A
10.	HEAT STABILITY :-	Stable ≤ 180 °C
11.	STORAGE STABILITY :-	Stable under normal condition
12.	METHODE OF ANALYSIS :-	HPLC
13.	LEVELS OF HARMFULL IMPURITIES:-	3%
14.	PHOTO DEGRADATION RATE	DT 50 1.5-33D
15.	HYDROLSIS RATE	Two weeks, DT 50 27 (ph4)

- Packaging :

Packaging details including full details of pack sizes, packaging, designs etc

Pack type :plastic bottles
Pack Size : 500Cm/1liter

- Use Pattern

Application Method	Dilution Rate (if applicable)	Application Rate
Spray		120cm/10 liter
By panting		32cm/10 liter

Pesticides efficacy

-Target Pests:- 1- for adult flies (spray) 2- for adult flies (by panting)

-Mode of Action on pest :-

Non-systemic insecticide and acaricide with contact stomach, and respiratory action .

Toxicological Studies:-

1-Acute mammalian toxicity:-

Acute Toxicity	Animal	LD ₅₀ (mg/Kg body weight)	
		Tech.	From.
Oral	Rat	1.828 mg/kg	
Dermal	Rabbit	≥2.000 mg/kg	
Inhalation mg/m ² /2H	rat	≥670 mg/m ³ – 4h	

- Symptoms:-

1- On Eye:- **mid (ref. FAO specification P30)**

2- on Skin :- **not sensitizer (ref. FAO specification P30)**

WHO Classification	Toxicity Category				Label Signal word		
	High.	Mod. II	Low III	Low IV	Danger	Warning	Caution
Tech. Form.		×				×	

2- Chronic Toxicity (reference) :-

Carcinogenicity (WHO) :- Rats were fed 0.1 and 1.0 mg/kg/day for two years. No spontaneous tumour incidence observed and it was concluded that chlorpyrifos-methyl is not carcinogenic. (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Teratogenicity (WHO):- Rats were fed dose levels of 50, 100 and 200 mg/kg/day on days 6-15 of gestation. No teratogenic effects were observed. A study on mice with doses up to 250 mg/kg/day for seven days on days 7-13 of gestation showed effects at highest dose level associated with decreased weight growth or maturation of the mouse. (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Mutagenicity(WHO): Not available

Delayed Neurotoxicity :- Hens surviving an oral dose of 4455 mg chlorpyrifos-methyl/kg were given both atropine, 10 mg/kg and PAM, 50 mg/kg intramuscularly as well as a second oral dose of 4555 mg chlorpyrifos-methyl/kg on the twenty-first day after first dose. The birds were held for a further 21 days during which no clinical signs of ataxia were observed. (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Hormonal Disruption(WHO): not available

Reproduction (WHO) Prolonged dietary administration of chlorpyrifos-methyl at levels of 1 or 3 mg/kg/day had no adverse effect on the reproduction capacity of either male or female rat. (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Acceptable Daily Intake(ADI):- not available.

3-Ecotoxicology (reference):-

1- Aquatic Organisms:- daphnia magna : EC₅₀= 0.16mg/l (ref WHO specification P41)

2- Honey Bees contact LD₅₀ = (48 hours) oral: 0.36mg/bee (ref WHO specification P41)

3- Birds mallard duck :chicken LD₅₀>2000mg/kg Bob white quail LD₅₀ 1835 mg/kg in diet Japanese quail LC₅₀>5000mg/kg in diet mallard duck LC₅₀ 2500-5000mg/kg in die (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Fish:- toxic to shrimp , craps and fish (WORLD HEALTH ORGANIZATION /FOOD AND AGRICULTURE ORGANIZATION ORGANISATION MONDIALE DE LA SANTE ORGANISATION POUR L'ALIMENTATION ET L'AGRICULTURE)

Section 4 - Safety Handling and Storage and Disposal

1- **Storage :-**

Keep in original container, tightly closed, in a cool dry and well – ventilated place, out reach of children, Avoid high temperature

2- **Shelf life :-** 2 years

3- **Handling precaution :-** Read the label before use, wear pesticides respiratory Masks, protective gloves and clothing while handling after handling wash water soap and water before eating/drinking / smoking

4- **Signs and symptoms of over Exposure :-**

Not Signs and symptoms of over exposure

5- **Note to Physicians :** this product is a cholinesteanase inhibition, non – systemic insecticides with contact stomach and respiratory action

6- **First Aid :-**

a. **If swallowed**

Call a poison control center immediately for treatment advice have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person

b. **If in eyes**

hold eye open and rinse slowly and gently with water for 15-20 minutes, remove contact lenses, if present after the 5 minutes then continue rinsing eye. Call a poison control center or doctor for treatment advice.

c. **If on skin**

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes Call a poison control center or doctor for treatment advice

d. **If inhaled**

move person to fresh air. If person is not breathing call ambulance. Then give artificial respiration, preferably mouth-to- mouth if possible. Poison control center or doctor for treatment advice

7- **Antidotes :-** Keep in original container, tightly closed, in a cool dry and well – ventilated place, out reach of children, Avoid high temperature

Section 5 - Product labelling.

Original label

Is an original label included?

- Yes** - Please attach an original pack.
- No** - Please provide a copy of your draft label.

Draft label or original pack

ICM-GROUP

Section 6 -DECLARATIONS

In relation to this submission, I certify that to the best of my knowledge that:

***The data & information have been reviewed & are certified to be true & accurate**

***All existing data which are relevant to the quality, safety and efficacy of the medicinal product will be supplied in the dossier, as appropriate**

***If the application is approved, I agree to comply with all applicable laws & regulations that apply to approved applications**

Signature of the Person authorized for communication on behalf of the applicant	Typed name & title Eng, Sherin Faheem	Date 26/9/2011	Official company stamp
Signature of the head of registration department of the applicant company	Typed name Eng, Mohamed Mostafa	Date 26/9/2011	