

**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 : Sherin Faheem | Telephone : 0224054744 |
| E-mail : registration@icm-eg.com.eg | Signature and date :26/9/2011 |

Section 2 - Product Information.

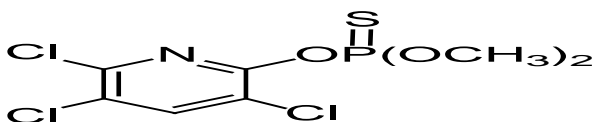
1-Pharmaceutical form : Emulsifiable Concentrate

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 |
| 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 :- | Inwater 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 | | 165cm/10 liter |

Pesticides efficacy

-Target Pests:- 1- for cockroach

-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/kg – 4h | |

- Symptoms:-

1- On Eye:- **mid (ref. WHO specification p13)**

2- on Skin :- **not sensitizer (ref. WHO specification p13)**

| 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 , crabs 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, ayman elshaffey | 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 | |