

**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\$ Trading (ICM)	International Center For Marketing & Trading (ICM)
Address	34, Mahmoud Khiary St. Nasr City-Cairo- Egypt	Badr City Industrial
Postcode	11717	
Registration Manager	Eng, Hossm mahmoud	Eng, Hossam Mahmoud
Telephone Number	0224054744	0224054744
Fax Number	0224054740	0224054740
Email Address	registration@icm-eg.com.eg	registration@icm-eg.com

Registration representative details:

Name : Sherin Fahiem	Telephone : 0224054744
E-mail : registration@icm-eg.com.eg	Signature and date :17 OCT. 2011

Section 2 - Product Information.

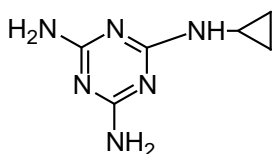
1-Pharmaceutical form : SOLUBLE LIQUID

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
N -cyclopropyl- 1,3,5-triazine-2,4,6- triamine	66215- 27-8	Cyromazine	Jinangxi Heyi Chemical Co.,	95%	10%	10%

Structural formula :-



Physical and chemical properties:

1. Physical form.	POWDER
2. Colour & Odour:-	YELLOW -ODERLESS
3. Molecular weight :	166.2
4. Vapor pressure:-	4.2X10 ⁻⁷ PA
5. M.P. or B.P. :-	219 – 220 °C/ N.A
6. Density	1.35gm/cm3
7. Solubility :-	In water 13G/L pH 7

(b)Other components of the formulation (inactive)

Name of component (IUPAC name)	CAS/EC Number	Trade Name	Function of Components	Conc %	Notes
Sodium Lauryl sulphate	61789-05-7	Wetting agent	Inactive ingredient	10%	
Kerosene	8008-20-6	Kerosene – odorless	Solvent	%80	

Section 3 - Product/Formulation Information

- Specification of formulations :-

APPEARANCE :- (PHYSICAL FORM)		LIQUID
1.	ALKALINITY OR ACIDITY :- (INCASE OF LIQUID)	N/A
2.	SUSPENSIBILITY: (INCASE OF SUSPENSION)	Soluble liquid
3.	EMULSIFICATION PROPERTIES :- (INCASE OF EMULSION)	-
4.	DENSITY :-	1.35(20 °C)
5.	VISCOSITY :-	N.A
6.	FLASH POINT :-	Does not flash
7. N.A	FREEZE POINT :-	N.A
8.	WETTABILITY :- (INCASE OF POWDER)	Be completely watted
9.	PARTICLE SIZE :-	N.A
10.	HEAT STABILITY :-	Stable up to 310 °C
11.	STORAGE STABILITY :-	Stable for hudrolysis for 28 days at up to 70 °C
12.	METHODE OF ANALYSIS :-	HPLC
13.	LEVELS OF HARMFULL IMPURITIES:-	5%
14.	PHOTO DEGRADATION RATE	Two weeks .DT50 75%-0%
15.	HYDROLSIS RATE	DT 50 6h (ph15)

- Packaging :

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

Pack type :plastic bottles
Pack Size /500Cm³/1liter

- Use Pattern

Application Method	Dilution Rate (if applicable)	Application Rate
Spray		200Cm ³ /10liter for larva flies

Pesticides efficacy

-Target Pests:- Larva flies

-Mode of Action on pest :-

Insect growth regulator, suppressor of embryogenesis with contact action which interferes with moulting and pupation.

Toxicological Studies:-

1-Acute mammalian toxicity:-

Acute Toxicity	Animal	LD ₅₀ (mg/Kg body weight)	
		Tech.	From.
Oral	rat	3387 mg/kg	
Dermal	rat	≥3100 mg/kg	
Inhalation mg/m ² /2H	rat	≥ 2720 mg/m ³ /4h	

- Symptoms:-

1- On Eye:- **mid** (FAO specification and evaluation for agriculture pesticides P12)

2- on Skin :- **not** (FAO specification and evaluation for agriculture pesticides P12)

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) :- rat (m.f) 24 month carcinogenicity and chronic toxicity 87/302/EEC B.33 - OECD 453(1981) FIFRA 83-5 (study predated the guidelines but would have been compliant); dietary administration; does 0.30.300ppm additional groups in control and highest dose group were fed control diet for a four-week recovery period prior to termination after 1 year of dosing purity 95.3 & 95.5% (FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 19)

Teratogenicity (WHO):- rat (f) 87/302/EEC B.31 - OECD 414 (1981) - FIFRA 83-3 (study predated the guidelines but would have been compliant) dosed by gavages on day 6-19 (inclusive) of gestation; does 0.100.300.600 mg/kg bw/d; purity 96.3% Cyromazine did not cause teratogenic effects. LOAEL= 300 mg/kg based on maternal & foetal weight and reduced ossification, clinical sig(FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 19)

Mutagenicity(WHO): *S typhimurium* TA1535 TA 1537 TA98 Ta100 in vitro gene mutation 67/548/EEC B.13/14 (2000) - OECD 471(1997) - OPPTS 870.5100 (1998); tests 1& 2.0 to 5000 ug/plate± S9 activation; purity 97.5% result Negative (FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 21)

Delayed Neurotoxicity :- not available

Hormonal Disruption(WHO): not available

Reproduction (WHO) rat (m.f) Oral (feeding) 2- generation reproduction 87/302/EEC B.35-OECD 416 (1983) - FIFRA S 83-4 (study predated the guidelines but would have been compliant); diet contained 0.30 1000 or 3000, ppm purity 95.3% - result = NOAEL (maternal = 2.0mg/kg bw/d (30 ppm) NOAEL (offspring) 65 mg/kg bw/d (1000ppm)LOAEL (maternal)= 65mg/kg bw/d (1000ppm) LOAEL = (offspring)= 215 mg/kg bw/d (FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 19)

Acceptable Daily Intake(ADI):- 0-0.06 mg/kg bw/d and an acute Rfd of 0.1 mg/kg bw (JMPR 2006). (FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 14)

3-Ecotoxicology (reference):-

1- Aquatic Organisms:- acute toxicity static EPA-660/3-75-009 (1975); doses 0.10 , 18 , 32, 56 or 100mg/l; purity 95.6% (FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 24)

2- Honey Bees contact acute oral & contact toxicity EPPO 170 (1992); single oral or topically applied dose; 48h observation; oral doses 0.80.120.1.200.240 or 280 ug/bee contact doses 0.25.50.100.150 or 200 ug/bee; purity 98% result oral LD₅₀ = 186 UG/BEE CONTACT LD₅₀ = >200 ug/bee(FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 24)

3- Birds mallard duck :sub-chronictoxicity & reproduction FIFRA Guidline 71-4 (1982) dietary inclusion for 19 week; doses 0.75.300 or 300 or 1200 mg/kg diet; purity 96.3% NOEL=300 mg/kg feed ((FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 23)

Fish:- channel catfish acute toxicity , static EPA 660/3-75-009 (1975); 96-h; does 0.10. 18.32.56 or 100 mg/l; purity 95.6% LC₅₀ > 100 mg/l NOEC= 100mg/l(FAO SPECIFICATIONS AND EVALUATION FOR AGRICULTURAL PESTICIDE page 23)

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 table 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 contract lenses, if present after the 5 minutes then conti7nue 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 :-** Sulfate Atropin

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 Faheim	Date 17/10/2011	Official company stamp
Signature of the head of registration department of the applicant company	Typed name Eng, Hossam Mahmoud	Date 17/10/2011	