APPLICATION FORM FOR REGISTRATION OF A BIOCIDAL PRODUCT(insecticide)

Code:	
Application No.:	
Submission Date:	
Submission Time:	
Receipt Number:	

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:**	.☒ Public Health	.☐ Household
A.2	**Market status:**	.☐ Export Only	.☒ Local
A.3	**Type of registration:**	.☐. Imported (finished product) .☒.local (formulated)	☐. Imported (bulk) ☐. 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, Hussam Mahmoud	Eng, Hussam Mahmoud
Telephone Number	0224054744	0224054744
Fax Number	0224054740	0224054740
Email Address	registeration@icm-eg.com.eg	registeration@icm-eg.com

Registration representative details:

Name : Sherin Faheem	Telephone : 0224054744
E-mail : registeration@icm-eg.com.eg	Signature and date :30 OCT. 2011

Section 2 - Product Information.

1-Pharmaceutical form

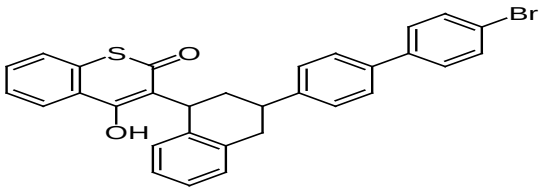
Solid

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
3-[3-(4'-bromo[1,1'biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one*	**104653-34-1**	**DIFETHIALONE**	**Nanjing Essence Fine Chemical**	**98%**	**0.0025%**	**0.0025%**

Structural formula :-



Physical and chemical properties:

1. Physical form.	Powder
2. Colour & Odour:-	Colour less / odorless
3. Molecular weight :	539.5
4. Vapor pressure:-	N.A
5. M.P. or B.P. :-	N.A – 200-210ºC
6. Density	N.A
7. Solubility :-	Insoluble

(b)Other components of the formulation (inactive)

Name of component (IUPAC name)	CAS/EC Number	Trade Name	Function of Components	Conc %	**Notes**
Wheat	**---**	**WHEAT**	**BASE**	**99.9975%**	

Section 3 - Product/Formulation Information

- Specification of formulations :-

APPEARANCE :- (PHYSICAL FORM)		**Solid**
1.	**ALKALINITY OR ACIDITY :- (INCASE OF LIQUID)**	**-9 at 20°C**
2.	**SUSPENSIBILITY: (INCASE OF SUSPENSION)**	**non**
3.	**EMULSIFICATION PROPERTIES :- (INCASE OF EMULSION)**	**Non**
4.	**DENSITY :-**	**Non**
5.	**VISCOSITY :-**	**non**
6.	**FLASH POINT :-**	**-176°C**
7.	**FREEZE POINT :-**	**-135°C**
8.	**WETTABILTY :- (INCASE OF POWDER)**	**Slightly soluble**
9.	**PARTICLE SIZE :-**	**-240**
10.	**HEAT STABILITY :-**	**- 50°C**
11.	**STORAGE STABILITY :-**	**Stable**
12.	**METHODE OF ANALYSIS :-**	**HPLC**
13.	**LEVELS OF HARMFULL IMPURITIES:-**	**3%**
14.	**PHOTO DEGRADATION RATE**	**DT50 (ph5)= 59.7min (28-35°C)**
15.	**HYDROLSIS RATE**	**Ph5 : > 1 years ph7 : 175 days 25°C**

- Packaging :

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

Pack type : plastic package
Pack Size : 500gm/1kg

- Use Pattern

APPLICATION METHOD	DILUTION RATE (IF APPLICABLE)	APPLICATION RATE
The pesticide is placed in the whereabouts of rats		1 KG / 200 M2 for rat control

Pesticides efficacy

- **TARGET PESTS**:- for rat control

- **MODE OF ACTION ON PEST** :-

Requires multiple feeding to produce lethal effects, use control of ratsina variety of situation including areas containing stored products

Toxicological Studies:-

1-Acute mammalian toxicity:-

Acute Toxicity	Animal	LD_{50} (mg/Kg body weight)	
		Tech.	From.
×Oral Dermal Inhalation mg/m^2/2H	RAT N.A N.A	≥5000 mg/k	

- **Symptoms:-**

1- On Eye:- not irritant (ref. WHO specification and evaluation for public health p44)

2- on Skin :- not irritant (ref. WHO specification and evaluation for public health p44)

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) :- -

There is no indication of any highr incidence of cancer in human following long term therapy with the closely related molecule - warfarin study difethialone waived

(REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 44) -

Teratogenicity (WHO):- DIFETHIALONE SHOWED NO MUTAGENIC POTENTIAL IN THE IN VITRO AND IN VIVO STUDIES WHICH HAVE BEEN PERFORMED

(REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 44). -

Mutagenicity(WHO):

DIFETHIALONE SHOWED NO MUTAGENIC POTENTIAL IN THE IN VITRO AND IN VIVO STUDIES WHICH HAVE BEEN PERFORMED (REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 44).

Delayed Neurotoxicity :- Difethialone was investigated, in various screeningtests for potential pharmacological activity other than its known anticoagulant properties. Difethialone showed no antianginal activity *in vivo* or *in vitro;* no antihypertensive activity; no sedative activity; no anticonvulsant activity; no antidepressant activity; no antispasmodic activity in a variety of *in vitro* tests and no analgesic, anti-inflammatory or gastric antiacid activity in various tests designed to investigate these endpoints. Difethialone, has a highly specific mode of action, blocking regeneration of vitamin K in the liver, and no other pharmacologic activity has been established for the molecule.

(REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 45).

Hormonal Disruption(WHO): not available

Reproduction (WHO):- Difethialone did not cause any observed teratogenic effects in experimental animal studies.

Rat

In the absence of effects on dams or foetuses and with no maternal mortality or signs of toxicity, no critical effects were identified at the doses used in the main study (up to 50 µg/kg bw/day). Maternal death resulting from haemorrhages was evident in a preliminary study (dosed at 50 or 70 µg/kg bw/day).

Rabbit

No embryofoetal toxicity and no developmental toxicity indicative of teratogenicity observed. Maternal toxicity: Haemorrhages, mortality

(REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 46). -

NOT APPLICATION (REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC Acceptable Daily Intake(ADI):- - HEALTH PESTICIDE PAGE 48).

3-Ecotoxicology (reference):-

1. Aquatic Organisms:- not available4.4mg/L (REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 51)
2. Honey Bees :- not appropriate (REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 52).
3. Birds : mallard duck : LD50= 0.264mg/kg bw ((REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 51).
4. Fish:- oncarhynchus mykiss 96 hours 51 mg/L(REF. WHO SPECIFICATION AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDE PAGE 51).

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** : not signs and symptoms of over exposure.

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 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

Antidotes :- Most acute rodenticides have no specific antidote, and in any event there is rarely sufficient time for poisoned individuals to reach medical care. Where sophisticated medical care is available, anticoagulant-exposed persons can be treated with vitamin K1.

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

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* *30/10/2011*	*Official company stamp*
Signature of the head of registration department of the applicant company	*Typed name* *Eng, Hussam Mahmoud*	*Date* *30/10/2011*	