

**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 : Sherien Fahiam	Telephone : 0224054744
E-mail : registration@icm-eg.com.eg	Signature and date :

Section 2 - Product Information.

1-Pharmaceutical form

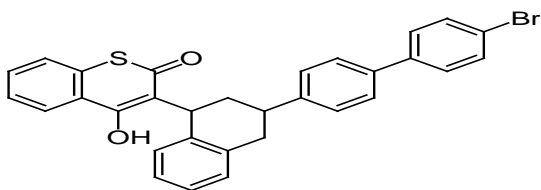
WAX

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
Brodifacoum	56073-10-0	Bay Bay Rat	Nanjing Essence Fine Chemical	>91%	0.005%	0.005%

Structural formula :-



Physical and chemical properties:

1. Physical form.	Powder
3. Colour & Odour:-	White Powder
5. Molecular weight :	523.4
7. Vapor pressure:-	$6 \times 10^{(-6)}$ mm/g at 68°F
9. M.P. or B.P. :-	130°F-N.A
11. Density	228-232°C
13. Solubility :-	Insoluble in water

(b)Other components of the formulation (inactive)

Name of component (IUPAC name)	CAS/EC Number	Trade Name	Function of Components	Conc %	Notes
WAX	---	WAX	Base	99.995%	

SECTION 3- PRODUCT / FORMULATION INFORMATION**- SPECIFICATION OF FORMULATION**

APPEARANCE :- (PHYSICAL FORM)		Wax
1.	ALKALINITY OR ACIDITY :- (INCASE OF LIQUID)	N/A
2.	SUSPENSIBILITY: (INCASE OF SUSPENSION)	N/A
3.	EMULSIFICATION PROPERTIES :- (INCASE OF EMULSION)	N/A
4.	DENSITY :-	1.42g/l 25 °C
5.	VISCOSITY :-	N/A
6.	FLASH POINT :-	>375 °C (paraffin wax)
7.	FREEZE POINT :-	N/A
8.	WETTABILTY :- (INCASE OF POWDER)	N/A
9.	PARTICLE SIZE :-	N/A
10.	HEAT STABILITY :-	(up to 50 °C)
11.	STORAGE STABILITY :-	Stable under normal use and storage conditions
12. HPLC	METHODE OF ANALYSIS :-	HPLC
13.	LEVELS OF HARMFULL IMPURITIES:-	9%
14.	PHOTO DEGRADATION RATE	30 d in direct sunlight) stable Degraded u.v light when in solution
15.	HYDROLSIS RATE	Degraded in soils (ph 5.5 to ph 8) under aerobic and flooded conditions

PACKAGING

PACKAGING DETAILS INCUDING FULL DETAILS OF PACK SIZE, PACKAGING DESIGNS ETC

PACK TYPE: Packages Plastic

PACK SIZE : 250gm /500gm/1 kg/5kgs/25kgs

USE PATCRN

APPLICATION METHOD	DILUTION RATE (IF APPLICABLE)	APPLICATION RATE
bait		1 kg/ 200m2

Pesticides efficacy**-Target Pests:-**

Rodent pests

-Mode of Action on pest :-

Indirect anticoagulant (acts by inhibiting the vitamin K epoxide reductase in the vitamin k1-epoxide cycle)

Toxicological Studies:-**1-Acute mammalian toxicity:-**

Acute Toxicity	Animal	LD ₅₀ (mg/Kg body weight)	
		Tech.	From.
Oral	Rat	≥5000mg/kg	
Dermal	N.A		
Inhalation mg/m ² /2H	N.A		

- Symptoms:-

1- On Eye:- slight irritation

2- on Skin :- irritation(rabbit)

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) :-**

No effect has been demonstrated with technical brodifacoum in carcinogenicity tests (ICI Ltd) (ref Anticoagulant rodenticides (EHC 175, 1995)htm)

Teratogenicity (WHO):- studies in rats and rabbits have demonstrated letotoxic embryotoxic or

Mutagenicity(WHO):

Reverse mutation *S. typhimurium* strains TA98, TA100, TA1535 and TA1537

20–12 500 µg/plate (±) S9 98.5 Negative Herbold (1986)

Gene mutation CHO K1-BH4 cells, *Hprt* locus

Genotoxicity not genotoxic in vitro or in vivo

(ref : Pesticide Residues in Food -2006- Joint FAO/WHO) Pesticide Residues Page 136)

Delayed Neurotoxicity :- Neurotoxicity Behavioural effects (increased motility, grooming and digging movements) Lowest relevant oral NOAEL 1 mg/kg bw (single and repeated dose by gavage, beta-cyfluthrin and cyfluthrin, rats)

(ref : Pesticide Residues in Food -2006- Joint FAO/WHO) Pesticide Residues Page 146)

Hormonal Disruption(WHO): not available

Reproduction (WHO):- Reproduction target/critical effect No reproductive effects (rats) Lowest relevant reproductive NOAEL 450 ppm, equal to 34.7 mg/kg bw per day, i.e. highest dose tested (cyfluthrin, rats)

(ref : Pesticide Residues in Food -2006- Joint FAO/WHO) Pesticide Residues Page 146)

Acceptable Daily Intake(ADI):- 04 mg/kg bw,

(ref : Pesticide Residues in Food -2006- Joint FAO/WHO) Pesticide Residues Page 143 ,144)

3- Ecotoxicology (reference):-

1. Aquatic Organisms:- not available
2. Honey Bees :- not available
3. Birds not available
4. Fish:- not available

Not other data

(ref : Pesticide Residues in Food -2006- Joint FAO/WHO) Pesticide Residues Page 146)

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 :

BEND SPECTRUM INSECTICIDES WILL CONTACT 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 :- 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.

ICM GROUP

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

<p>البيانات التحذيرية : في حالة التسمم العقار المضاد هو Vitamin K1 في حالة التسمم الشديد ينقل المريض الي اقرب مركز لعلاج السموم</p> <p>بيانات تحذيرية عن مخاطر المركب:</p> <p>1 - عدم ملاسة المستحضر للعين 2 - عدم استنشاق المستحضر. 3 - عدم ملاسة المستحضر للجلد. 4 - عدم بلع المستحضر احتياطات الامان الاسعافات الاولى :</p> <p>1 - يجب ارتداء الملابس الواقية اثناء رش المبيد 2 - تجنب تطاير المبيد اثناء الرش او اثناء او تعبئة اجهزة الرش الى الجلد . 3 - يجب عدم الرش على مياه الشرب او المجارى المائية او مصادر المياه الاخرى 4 - يجب عدم تناول الاطعمة والمشروبات او التخزين اثناء الاستعمال 5 - فى حالة تلوث الجلد يغسل جيدا بالماء والصابون وفى حالة تلوث العين تغسل جيدا بالماء لمدة 15 دقيقة . طريقة الحفظ و التخزين : يحفظ فى العبوات الاصليه بعيدا عن ضوء الشمس وفى مكان جيد التهوية . يحفظ فى درجة حرارة لا تتعدى 30 درجة</p>	<p>باي باي رات (شمع) Bay Bay rat(WAX) مبيد حشري صحة عامة</p> <p>التركيب : برودينفاكوم 0.005% شمع 99.995% 100%</p> <p>المستحضر فى صورة مكعبات شمع يحتوى الكيلو جرام منه على 0.05 مادة فعالة</p> <p>البيانات التحذيرية تحذير مادة سامة تحفظ بعيدا عن تناول ايدي الأطفال إنتاج وتصنيع المركز الدولي للتسويق والتجارة نموذج 81/80 بالدور الثاني مدينة بدر الصناعية ت / 024054744</p>	<p>الاستخدامات للقضاء على القوارض</p> <p>طرق الاستخدام : 1 كجم / 200 م² فى اماكن تواجد الفئران</p> <p>تضمن الشركة المركب لمدة عامان على ان يتم حفظه فى العبوات الاصليه بعيدا عن ضوء الشمس فى مكان جيد التهوية.</p> <div data-bbox="1069 929 1364 1131" style="border: 1px solid black; padding: 5px;"><p>رقم التسجيل بوزارة الصحة: تحت التسجيل رقم التشغيل : تاريخ الانتاج : 2010/4 تاريخ الانتهاء : 2012/4 سعة العبوة:</p></div> <p>مدة الصلاحية: عامين من تاريخ الانتاج</p>
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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 1/10/2010	Official company stamp
Signature of the head of registration department of the applicant company	Typed name Eng, Mohamed Mostafa	Date 1/10/2010	