

2724-461

02/26/2009

1/7



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Nancy Huebl
Product Registration
Wellmark International
1501 Woodfield Road, Suite 200W
Schaumburg, IL 60173

FEB 26 2009

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request Directions for Use Change
EPA Reg. No. 2724-461 January 29, 2009

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 01/29/09 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-461	2. EPA Product Manager Richard Gebken/M. Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Sandoz 9023 Fly Bait Station	PM # 10	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>FEB 24 2009</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Label notification to revise sentence to clarify not to "crush" ampoule but "squeeze" until snap to avoid loss of liquid inside
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
			1-2	<input checked="" type="checkbox"/> Other (Specify)	foil pouch in cardboard
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 or 2 bait strips		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled	<input checked="" type="checkbox"/> Other printed cardboard carton	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
2. Signature <i>Nancy Huebl</i>		6. Date Application Received (Stamped)
3. Title Senior Registration Specialist		
4. Typed Name Nancy Huebl	5. Date 29-Jan-09	

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

Wellmark

January 29, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

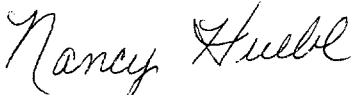
ATTENTION: Richard Gebken, PM 10

SUBJECT: SUBMISSION OF NOTIFICATION PER PRN 98-10
SANDOZ 9023 FLY BAIT STATION/EPA REG. NO. 2724-461
REVISE AMPOULE BREAKING SENTENCE

Dear Mr. Gebken:

Enclosed is a completed EPA Form 8570-1 and 1 highlighted copy of the revised label. Due to a number of complaints for this product that the attractant ampoule is being "crushed" per the current directions, we are revising the sentence to more appropriately specify that the user should "Squeeze the attractant ampoule tube until a snapping sound is heard..." in order to avoid the leaking of the liquid attractant. I have enclosed a self-address postcard for notification confirmation. Please call me at 847-330-5376 if you have any questions regarding this submission. Thank you for your assistance on this action.

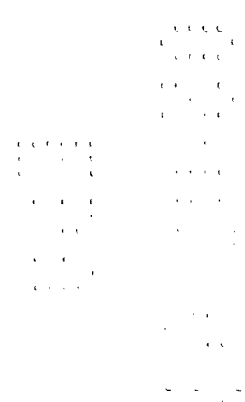
Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Senior Registration Specialist

enclosure

cc: S. Spaulding/J. McFadden/C. Elmi/H. Friedli



[] Indicates optional marketing text

SANDOZ 9023 FLY BAIT STATION

- Kills flies [dead] within seconds
- Attracts flies within 300 ft² area
- Single application kills flies up to 8 weeks [56 days]
- Attracts and kills male and female nuisance flies from all directions
- Advanced patented triple action attractant
- Self-Contained Attractant
- Easy to use
- Compatible with IPM programs
- No bioaccumulation in the environment

ACTIVE INGREDIENT:

Nithiazine [2H-1, 3-thiazine, tetrahydro-2-(nitromethylene)] 1%

OTHER INGREDIENTS: 99%

Total 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautions

NOTIFICATION

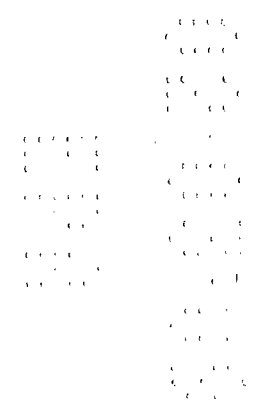
FEB. 24 2009

NET CONTENTS: X stations [bait strips]

EPA Reg No. 2724-461
EPA Est. No.

PRECAUCION AL USUARIO:

Si usted no lee ingles, no use este producto hasta que la etiqueta haya sido explicada ampliamente.



The Sandoz 9023 fly bait station contains a unique active ingredient that controls nuisance flies through ingestion. The active ingredient is contained in a sugar-based matrix that flies find irresistible. Flies will land on the station and begin exploring the surface. Once the flies locate the sugar, they will begin feeding. Shortly after feeding, the flies will begin to die.

The Sandoz 9023 fly bait station may be placed at locations where flies are a problem. For optimum results, place the station low to the ground, flies generally forage for food close to the ground. Flies seen at higher locations are resting and not actively seeking food. Bait stations placed in rafters or areas higher than 4 feet will not be as effective. Place the bait station on a stationary object. Do not allow the bait station to blow in the wind, as flies will not land on moving objects. Affix the station using suitable adhesive that will keep the station in place for the duration of the product's life. The station may be placed at any angle but is most effective when placed on a flat surface. In areas of low to moderate infestations, the station will provide control, but control may be less apparent. The fly bait station contains a triple action fly attractant that, when activated, will attract flies to the area.

The Sandoz 9023 fly bait station should be protected from moisture and direct sunlight, when possible. Excessive moisture will reduce the residual life of the Sandoz 9023 fly bait station. Sandoz 9023 fly bait station can be attached to dumpsters, refuse bins, garbage chutes, poles, feed bunks, walls, fences, and other surfaces out of the reach of children and animals. The Sandoz 9023 fly bait station is most effective against house flies (*Musca domestica*) and the lesser house fly (*Fannia culicularis*). The active ingredient is contained in a sugar-based matrix that is the yellow portion of the fly bait station.

The Sandoz 9023 fly bait station can be used in a variety of areas. Examples of placement locations are: garbage chutes, dumpsters, loading docks, waste containers, grease pits, rest areas, outdoor rest room facilities, in and around stables, dairy barns, milking parlors, loafing sheds, kennels, poultry houses, aviaries, swine houses, feedlots, refuse and recycling facilities, around commercial food-handling facilities, restaurants, bars, groceries, stores, and other facilities where house flies are a nuisance.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Avoid contact with eyes.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with the labeling.

In enclosed structures or sites with low to moderate house fly populations, use 1 station [strip] per 300 ft². In open structures or sites with high house fly populations, use 1 station [strip] per 100-150 ft². Ventilation will not diminish Sandoz 9023 fly bait station's effectiveness since it works by fly feeding action.

Remove the Sandoz 9023 fly bait station [strip] from the protective pouch. Handle by grasping ~~corner tabs~~ curved ends of strip.

The product contains 1 attractant container on the fly bait station. ~~Crush~~ Squeeze the attractant ~~container~~ ampoule tube until a snapping sound is heard at time of application. Note: This attractant has a strong odor.

For best results, hang or affix device close to fly forage areas out of reach of children and animals. Place fly bait station close to the ground in areas that are inaccessible to children and animals. Avoid placement of strip in locations higher than 4 feet above the ground.

Do not place where daily activity will get stations [strips] wet.

Replace when effectiveness diminishes.

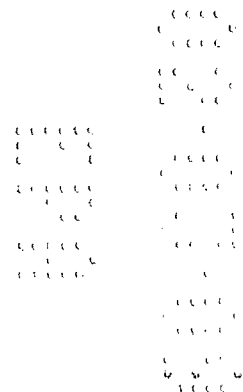
STORAGE AND DISPOSAL: Store in a cool dry place away from children and animals. To dispose, wrap in newspaper and put in trash.

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in an emergency, call [phone number] or visit our Web site: [URL]

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, IL 60173

Made in USA



**SANDOZ 9023 FLY BAIT STATION
2724-461
INDIVIDUAL DEVICE LABELING CONTENT**

Name, Brand, or Trademark

Wellmark International
1501 East Woodfield Road 200W
Schaumburg IL 60173
[phone number]

EPA Reg. No. 2724-461

Ingredient Statement:

Active Ingredient: Nithiazine [2H-1, 3-thiazine, tetrahydro-2-(nitromethylene)].....	1%
Other Ingredients:	<u>99%</u>
TOTAL:	100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Refer to outside package for specific First Aid, Precautionary Statements, and Directions for Use

Precautionary Statement: CAUTION: Avoid contact with eyes.

Disposal: Wrap in newspaper and put in trash.

**NOTIFICATION
FEB 24 2009**

