

2724-461

4-26-2000

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United States Environmental Protection Agency

Ms. Nancy Huebl, Regulatory Label Specialist  
Wellmark International  
1000 Tower Lane, Suite 245  
Bensenville, IL 60106

APR 26 2000

Subject: Label amendment to expand and clarify the general information and Directions for use.  
Product Name: Sandoz 9023 Fly Bait Station  
Registration No.: 2724-461  
Submission dated: March 8, 2000

Dear Ms. Huebl,

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below.

1. Page 1
  - a. The replacement of "300" with a "#" indicator within the product attribute claim "Attracts flies within 300 ft<sup>2</sup> area" is non specific and may be considered a false and misleading statement under 40 CFR 156.10(a) (5). Any claims greater than the currently approved language must be supported with efficacy data, and specific ft<sup>2</sup> values.
  - b. PR Notice 97-5 specifically lists those pesticides that are allowed to be identified in the "Active Ingredient" section by common name only. Nithiazine (CAS # 58842-20-9) is not listed, and therefore, the common name must be succeeded by the previously approved chemical name "2H-1,3 thiazine,tetrahydro-2-(nitromethylene)". Wellmark may add "CAS # 58842-20-9" provided it is added as a footnote to the primary active ingredient nithiazine. Wellmark may do so without notification to EPA (a "non-notification" under 40 CFR 152.46) as outlined in PR Notice 97-5. A copy of the PR notice is available on the Agency web site at the following URL address:  
[http://www.epa.gov/opppmsd1/PR\\_Notices/pr97-5.html](http://www.epa.gov/opppmsd1/PR_Notices/pr97-5.html).
2. Page 4 "Individual Device Labeling Content"
  - a. Insert the language "Keep out of Reach of Children"
  - b. Insert the language "Refer to outside package for specific First Aid, Precautionary Statements, and Directions for Use."

Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

Sincerely,

  
Marion Johnson  
Product Manager 10  
Insecticide Branch  
Registration Division (7505C)

enclosure

CONCURRENCES

SYMBOL ▶	H7505C							
SURNAME ▶								
DATE ▶	Apr 26, 2000							

[ ] Indicates optional marketing text

### SANDOZ 9023 FLY BAIT STATION

- Kills flies [dead] within seconds
- Attracts flies within [#] ft<sup>2</sup> 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 (CAS #58842-20-9) ..... 1%

**OTHER INGREDIENTS:** ..... 99%

Total ..... 100%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See Back Panel for Additional Precautions

**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.

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
APR 26 2000**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
2724-461**

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**

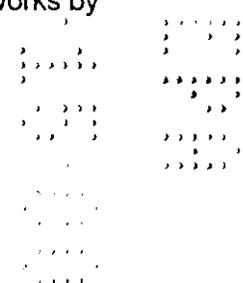
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION:** Avoid contact with eyes.

**FIRST AID**

**If in Eyes:** Hold eyelids open and flush with plenty of water. Get medical attention if irritation persists.

**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 ft<sup>2</sup>. In open structures or sites with high house fly populations, use 1 station [strip] per 100-150 ft<sup>2</sup>. 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.

The product contains 2 attractant containers on either end of the fly bait station. Crush 1 attractant container at time of application. Wait at least 3-4 weeks and crush second attractant container. At the same time, reverse the fly bait station if it has been applied to a flat surface to reveal the unexposed side to flies.

Note: These attractants have 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

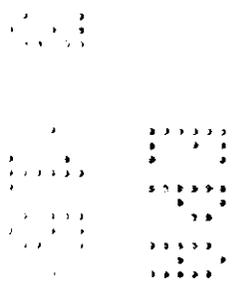
**STORAGE AND DISPOSAL:** Store in a cool dry place away from children and animals. To dispose, wrap in newspaper and put in trash.

Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk 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]

Wellmark International  
Bensenville, IL 60106

Made in USA



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

Name, Brand, or Trademark

**Wellmark International**  
**Bensenville IL 60106**  
[phone number]

EPA Reg. No. 2724-461

Ingredient Statement:

<b>Active Ingredient:</b> Nithiazine .....	1%
<b>Other Ingredients:</b> .....	99%
<b>TOTAL:</b> .....	100%

**Precautionary Statement: CAUTION:** Avoid contact with eyes.

**Disposal:** Wrap in newspaper and put in trash.

