

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 *M* St., S.W.
Washington, D.C. 20460

3125-546

EPA Reg. Number:

Date of Issuance:

DEC -- 7 2000

NOTICE OF PESTICIDE:

x Registration

Reregistration

Name of Pesticide Product

KBR 3023 All-Family Insect Repellent Cream II

Term of Issuance: Conditional

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Bayer Corporation

Garden & Professional Care

Box 4913

Kansas City, MO 64120-0013

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec.3(c)(7)(C) since you agreed in your letter dated December 6, 2000 that:

- 1. You will submit by March 1, 2001 the protocol and locations for conduct of the 2001 market test for 2,000 human subjects.
- 2. You will submit by April 15, 2001 the final complete results of the 90-day rat subchronic oral study conducted in accordance with the 40 CFR Part 158 test guidelines.
- 3. You will submit/cite all data required for registration/reregistration of your product under FIFRA section 3 (c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 4. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the use as a human skin applied insect repellent is conditionally registered, in accordance with FIFRA section 29. This fiscal year begins October 1, 2000 and ends September 30, 2001. The production information will be submitted to the Agency no later than November 15, 2001 following the end of the preceding fiscal year.

PMITBIRD

Signature of Approving Official:

Date:

DEC

7 2000

EPA Form 8570-6

- 5. You will submit by December 1, 2001 to submit the results of the marketing test with up to 2,000 human subjects.
- 6. You will report adverse effects information resulting from use of any of the subject end-use products as required by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- 7. You will submit by December 1, 2001 all product performance data collected during the conduct of the 2001 market test.
- 8. You will submit within 7 days of receipt of this conditional registration a revised basic Confidential Statement of Formula (CSF) for the subject product. The nominal concentration of the picaridin technical source on the Confidential Statement of Formula (CSF) for the subject product must reflect the identical concentration of 96.8 percent as depicted on the picaridin technical label and CSF. Provide the Flash Point/Flame Extension value on the CSF. Revise the respective Confidential Statement of Formula to reflect this change.

This information should be submitted to:

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U.S. Environmental Protection Agency Office of Pesticide Programs (7504C) Document Processing Desk Ariel Rios Building 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

- 9. Make the following label changes before you release the product for shipment:
 - a. Revise the EPA Registration No. to read: "EPA Registration No. 3125-546"
- 10. Submit two (2) copies of your final printed labeling before you release the product for shipment.

You should note if you fail to satisfy any of the conditions imposed on this registration, e.g., you fail to submit the required data by the specified deadlines or the data submitted were not generated in accordance with applicable test guidelines, EPA may issue notice to cancel this use under FIFRA 6(e).

You should also note that, regardless of whether you satisfy all applicable conditions, this conditional registration will expire automatically on December 1, 2001. Sale and distribution of the subject product bearing labeling for use as a human skin applied insect repellent after December 1, 2001 will be illegal.

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Finally, once the required data have been submitted and evaluated, EPA will entertain an application to amend the registration of the subject product to allow unconditional use as a human skin applied insect repellent without any special restrictions on the duration of registration.

A stamped copy of the label is enclosed for your records.

Sincerely

Marion J. Johnson, Jr.
Product Manager (10)
Insecticide Branch
Registration Division (7505C)

KBR 3023

NEW!

ALL-FAMILY INSECT REPELLENT CREAM II

Contains Bayrepet™ new generation insect Repellent.

- · Effective protection from mosquitoes, biting flies and fleas.
- · Repels insects for up to 3 to 4 hours.
- Use with confidence on the whole family, it feels good on the skin, not oily, greasy or sticky. It smells great, too.

STOP - Read This Entire Label Before Use KEEP OUT OF REACH OF CHILDREN

CAUTION

Ingredients:

ACTIVE INGREDIENT:	
Picaridin*	%
OTHER INGREDIENTS** 95	%
TOTAL:	%

*Picaridin is the common chemical name for Bayrepel™.

**Other Ingredients: Purified water, glycerin, denatured alcohol, glycerin, emollient (for improved skin feel), fragrance, and thickeners.

Net Contents: 4 Ounces (113.5 grams)

EPA Reg. No. 3125-XXX

EPA Est. No. XXXX-AA-XX

PRECAUTIONARY STATEMENTS		
CAUTION	Hazards to Humans	
l	Causes moderate eye imitation. Avoid contact with eyes.	
	Avoid contact with lips, cuts or irritated skin. Do not apply to excessively sunburned skin.	

FIRST AID	
In the case of accidental	IMMEDIATELY
Contact with eyes	If in eyes: Hold eye open and rinse eye slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
	Call a poison control center or doctor for further treatment advice.
Ingestion	If swallowed: Call a poison control center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to by a poison control center or doctor.

Note: When calling poison control center, have this product label accessible. If advised to seek treatment at an emergency room or physician's office, bring this product label to show medical personnel. You may call Bayer at 800-414-0244 for more information.

Active Ingredient: Picaridin, CAS # 119515-38-7

ACCEPTED
with COMMENTS
In EPA Letter Dated:

DEC 7 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Res. No.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For best results, read and follow all label directions.

Storage Conditions	Store in a cool, dry place out of the reach of children.
Disposal	Do not reuse empty container. Discard in trash.

APPLICATION DIRECTIONS

Follow these guidelines when applying KBR 3023 Insect Repellent

- · Apply evenly to skin in a thin layer.
- · Reapply every 3 to 4 hours. Excessive amounts or more frequent reapplication should be unnecessary. Do not apply more than 3 times a day.

When using product on children, please mind the following:

- To apply to children, do not apply to their hands use your hands to apply the product to the child. Take care to avoid mouth and eyes, and apply sparingly around their ears.

 Do not allow children to handle the product.

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Reason to Issue: To propose registration of new product.

1 • Draft 11/06/00: To revise in accordance with EPA : comments.

Bayer Corporation Garden & Professional Care Box 4913 Kansas City, MO 64120-0013 Product Information: (800) 842-8020

