

PM 4 67517-65

2/23/98

1/5



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

S 517900
300/18

FEB 23 1998

Joseph E. Dyer, Regulatory Agent
PM Resources, Inc.
13001 S. Charles Rock Rd.
Bridgeton, MO 63044

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Bromethalin Liquid Concentrate 1.5%
EPA Registration No. 67517-65
Application for Amended Registration dated January 14, 1997

Dear Mr. Dyer,

Your application for amended registration for EPA Reg. No. 67517-65, dated January 14, 1997, and the proposed revised labeling submitted with your application have been reviewed. Your application and revised label are acceptable provided you 1) submit or cite efficacy data for this product, as discussed below, and 2) modify your label as indicated below.

1. According to our records, the only Confidential Statement of Formula (CSF) ever accepted for this product was the CSF dated "2/24/83". The only formulation that may be used for this product is the one described by that CSF.

Our records do not show a clear listing of efficacy data supporting the registration of this product as described by the CSF dated 2/24/83. You must submit or cite efficacy data which indicate that this product can be used to make effective rodenticide baits. For any efficacy data cited, you must be able to document that this product's current accepted formulation (CSF dated 2/24/83) was used in the preparation of the bait(s) that were tested. If the data are "owned" by another entity and eligible for data compensation, we will need written authorization from that entity to permit us to consider their relevant data.

2. Please make the following changes to your proposed label:
 - a. Replace the "NOTE TO FORMULATORS:" with a "DIRECTIONS FOR USE" section. This new section should read as indicated immediately below.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

DIRECTIONS FOR USE

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

This product may be used only to formulate end-use rodenticide baits which are to be used for any or all of the following purposes:

- 1. uses to control Norway rats, roof rats, and house mice in and around homes, industrial and agricultural buildings, similar man-made structures, inside transport vehicles (ships, trains, aircraft), in and around related port or terminal buildings, and in alleys located in urban areas;
- 2. uses for which the U.S. Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. uses for Experimental Use Permits that are in compliance with the requirements of the U.S. Environmental Protection Agency.

The exact content of the first-listed item in these use directions might have to be adjusted to be consistent with the labels of such products, if any, which contain the 67517-65 concentrate and are supported by accepted efficacy data.

- b. On the center panel of the label, replace

FOR FORMULATION ONLY INTO REGISTERED RODENTICIDES

with

FOR FORMULATION ONLY INTO END-USE RODENTICIDE BAITS AS DESCRIBED IN THE DIRECTIONS FOR USE WHICH APPEAR ON THE SIDE/BACK PANEL.

- c. Replace the "ENVIRONMENTAL HAZARDS" statement with the statement specified by PR Notice 93-10 for manufacturing use

3/5

products as follows:

"ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and other wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

- d. In the fifth sentence under **"PRECAUTIONARY STATEMENTS"** change "breath" to "breathe."

When revising your label, retain the organizational format proposed in your submission of January 14, 1997. Note that the heading for the **"DIRECTIONS FOR USE"** section should be centered as it must be parallel to the other major headings (e.g., **"PRECAUTIONARY STATEMENTS"**, **"ENVIRONMENTAL HAZARDS"**, **"STORAGE AND DISPOSAL"**, etc.).

Please submit or cite the requested efficacy data and one copy of your revised final printed labeling before you release the product for shipment. If the above specified conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. If you have any questions about this letter, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault
Chemical Manager, Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure (1)

415

ACCEPTED
with COMMENTS
In EPA Letter Dated:

Feb. 23, 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
67517-65

FRONT PANEL

BROMETHALIN LIQUID CONCENTRATE 1.5%

FOR FORMULATION ONLY INTO REGISTERED RODENTICIDES

ACTIVE INGREDIENT:

Bromethalin: N-methyl-2,4,-dinitro-N-(2,4,6-tribromophenyl)- 6-(trifluoromethyl) benzenamine.....	1.5%
INERT INGREDIENTS.....	98.5%
TOTAL	100.0%

KEEP OUT OF THE REACH OF CHILDREN
WARNING
SEE SIDE/BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

REC'D
JAN 22 11:32
7JPD1

EPA Reg. No.: 67517-65

EPA Est. No.: 67517-MO-1

NET WT.: 150 Kilograms

Manufactured By
PM RESOURCES, INC.
13001 St. Charles Rock Road
Bridgeton, MO 63044

(Lot/Code/Product/Rev. Numbers as needed) Mfg. & Printed in U.S.A.
Precautionary Labeling Must Meet Type Size and Prominence Requirements.

JK

SIDE/BACK PANEL

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed or inhaled. May cause eye irritation. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Do not breath vapor spray mist. In the case of cleanup following a spill, wear protective clothing and appropriate equipment to prevent exposure of skin and eyes and to prevent ingestion or inhalation.

STATEMENT OF PRACTICAL TREATMENT

If **Swallowed**: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do no give anything by mouth and do not induce vomiting.

If **Inhaled**: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If **In Eyes**: Flush eyes with plenty of water. Call a physician if irritation persists.

If **On Skin**: Wash with plenty of soap and water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in a cool, dry place. Keep containers closed and away from foodstuffs and other chemicals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty containers. Dispose of container in a sanitary landfill or by incineration if allowed by state or local authorities. If burned stay out of smoke.

NOTE TO FORMUATORS: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

NOTICE OF WARRANTY

PM RESOURCES, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORD WITH THE STATEMENTS MADE ON THIS LABEL.