



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
12455-88

Date of Issuance:
October 10, 1997

NOTICE OF PESTICIDE:
 x Registration
 Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
TECHNICAL BRODIFACOUM

Under FIFRA, as amended:

Name and Address of Registrant (include ZIP Code):

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704
Attn: Steven G. Oaks, Ph.D.

S 519548
S 521442
S 531563
166/12

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)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. Please note that the Reregistration Eligibility Decision (RED) for Brodifacoum will be issued shortly and you should receive a copy of the RED and the generic and product-specific Data Call-Ins (DCIs). Your technical product and all registered end-use products are subject to the requirements of the Brodifacoum RED and DCIs and you must submit acceptable responses within the timeframe(s) provided in the RED. If you do not receive copies of the RED and both DCIs, please contact Frank Rubis (SRRD/Reregistration Branch I) at (703) 308-8184.

continued on p.2

Signature of Approving Official:

Reg. Personnel

Date

10/10/97

2. On your proposed labeling submitted August 27, 1997 make the labeling changes listed below before you release the product for shipment.

a. Revise the EPA Registration Number to read, "EPA Reg. No. 12455-88.

b. The "**STATEMENT OF PRACTICAL TREATMENT**" on your proposed label must be amended to read exactly as follows:

"If Swallowed: Call 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 not give anything by mouth and do not induce vomiting.

If on Skin: Wash with plenty of soap and water. Get medical attention.

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."

c. The "**NOTE TO PHYSICIAN**" section that appears on the left panel of your proposed label should be moved to a position just below the last Statement of Practical Treatment (on the front panel, if it fits, or at the top of the left panel), but should be clearly distinguished from the Statements of Practical Treatment. In addition, in the second sentence of the "**NOTE TO PHYSICIAN**" section, replace the phrase "In such cases" with "If poisoning occurs," and add the words "and orally" in between "intramuscularly" and "in mild cases" (i.e. "intramuscularly and orally in mild cases").

d. Below the "**NOTE TO PHYSICIAN**" section, add an emergency telephone number to call for specialized medical advice.

e. On the left panel of your proposed label, the statement "**HAZARD TO HUMANS AND DOMESTIC ANIMALS**" should be left-justified so it is clear that this is a subheading subordinate to the heading "**PRECAUTIONARY STATEMENTS.**" The paragraphs under "**PRECAUTIONARY STATEMENTS**" must also be left-justified and the first paragraph must be revised to read as follows:

"**DANGER:** Fatal if swallowed, absorbed through the skin, or inhaled. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Do not breathe dust. For handling activities, use dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) and wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse. Exposure to this product during pregnancy should be avoided."

- f. In the next paragraph under "**PRECAUTIONARY STATEMENTS**," beginning with "Repeated exposures," replace the word "accumulative" with "cumulative."
- g. Amend the "**ENVIRONMENTAL HAZARDS**" statement, as required by PR Notice 93-10, to read as follows:
 - "This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."
- h. Delete the statement "**KEEP AWAY FROM FOODSTUFFS**" that appears above the "**DIRECTIONS FOR USE**" on your proposed label.
- i. The "**DIRECTIONS FOR USE**" portion of the label proposed for this product on August 27, 1997 is acceptable from the standpoint of efficacy. In the second paragraph, there should be a semicolon (;) rather than a comma between "alleys" and "in sewers."
- j. Under "**STORAGE AND DISPOSAL**," amend the "**STORAGE**" statement to read:

"**STORAGE:** Store in a locked storage area in a dry place. Store only in original container. Keep container closed when not in use. Do not store near food or feed."

- 3. Submit two copies of your revised final printed labeling before you release the product for shipment.
- 4. A copy of our review of the product chemistry data submitted for Technical Brodifacoum was attached to our letter dated March 4, 1997. The product chemistry review indicated that your technical contains fewer impurities than Zeneca's Brodifacoum Technical, therefore the two technical products are not considered chemically similar. However, a subsequent toxicology review indicated that the two technical products are considered toxicologically similar and that, with the exception of the product chemistry data discussed below, no additional data would be required for Bell's Technical Brodifacoum at this time (based on Bell's citation of existing generic data).

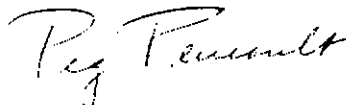
The product chemistry review for Technical Brodifacoum listed stability data (63-13) and vapor pressure (63-9) as data gaps. You have submitted a stability

study (MRID 442403-01) which is currently in review. Please note that the registration of this product is conditional upon the conclusions of our review of the stability study. The requirement for vapor pressure data is still outstanding. **Within 30 days of receipt of this letter you must indicate, in writing, how you intend to address this data gap (i.e. commit to conduct a vapor pressure study, cite appropriate published literature, etc.).**

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 regarding this notice, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault
Product Management Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS
DANGER**

Fatal if swallowed, absorbed through the skin, or inhaled. Do not get in eyes, on skin, or on clothing. Do not inhale powder. When mixing or handling, wear dust respirator, eye goggles, or face shield and rubber gloves. Wash arms and face with soap and water after mixing or handling and before eating or smoking. Exposure to this product during pregnancy should be avoided.

Repeated exposures to small amounts of this product can produce accumulative toxicity. Persons at risk should have their prothrombin times checked periodically.

NOTE TO PHYSICIAN: If swallowed, absorbed, or inhaled by humans, domestic animals or pets, this material will reduce the clotting ability of the blood and cause bleeding. In such cases, treat as in bishydroxycoumarin overdoses, giving Vitamin K₁ intramuscularly in mild cases or intravenously with blood transfusions in severe cases. Repeat as necessary, based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Keep out of lakes, streams, or ponds. Do not discharge to surface water or waste water treatment systems.

KEEP AWAY FROM FOODSTUFFS

DIRECTIONS FOR USE

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

For use only to formulate rodenticide baits which may be used to control Norway rats, roof rats, and house mice in and around homes, industrial, commercial, agricultural and public buildings, and similar manmade structures; in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings; in alleys, in sewers; and other use sites which may be approved by the U.S. Environmental Protection Agency on a case by case basis.

TECHNICAL BRODIFACOUM

**A RODENTICIDE FOR
FORMULATING USE ONLY**

ACTIVE INGREDIENTS:

Brodifacoum 3-[3-(4'-Bromo-1,1'-biphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2'-1-benzopyran-2-one... 98.0%
INERT INGREDIENTS..... 2.0%
TOTAL 100.0%

**KEEP OUT OF REACH OF CHILDREN
DANGER — POISON**



STATEMENT OF PRACTICAL TREATMENT

If swallowed — drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or blunt object. Avoid use of all oils. Have patient lie down and keep warm. Do not induce vomiting or give anything by mouth to an unconscious person. Get medical attention.

If on skin - wash with plenty of soap and water.
If in eyes - flush with plenty of water.
Get medical attention if irritation persists.
If inhaled - remove to fresh air.

See left panel for additional precautionary statements.

MANUFACTURED BY:



Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

EPA Est. No. 12455-WI-1 EPA Reg. No. 12455-

Net Contents 1 lb.

STORAGE AND DISPOSAL

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

STORAGE: Store only in original container in a dry place, inaccessible to children and pets.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Oct. 10, 1997

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

12455 80

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