

112701
SHAUGHNESSEY NO.

16
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 8/24/81 OUT 11/19/81

FILE OR REG. NO. 10182-38, -39, 40, -41

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 7/22/81

DATE RECEIVED BY HED 8/20/81

RD REQUESTED COMPLETION DATE 10/30/81

EEB ESTIMATED COMPLETION DATE _____

RD ACTION CODE/TYPE OF REVIEW 310/Amendment -- Me-Too

TYPE PRODUCT(S): I, D, H, F, N, R, S Rodenticide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Talon -G

COMPANY NAME ICI Americas, Inc

SUBMISSION PURPOSE Proposed Conditional Registration of outdoor use

For commensal rodents

SHAUGHNESSEY NO.

CHEMICAL, & FORMULATION

% A.I.

112701

Brodifacoum

0.005

Brodifacoum (Talon-G)

100.0 Pesticide Label Information

100.1 Pesticide Use

For control of Norway Rats, Roof Rats and House mice in and around homes, industrial, commercial, public and agricultural buildings. Talon may also be used inside transport vessels (ships, trains, aircraft) and in and around related port or terminal buildings. Treated baits must be placed in tamper-proof bait boxes or in locations not accessible to children, pets, domestic animals, or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

100.3 - 101.7 See Previous Review

102 Behavior in the Environment

See Fate Reviews
Deferred to fate Acc. #'s 245556 and 245705

103 Toxicological Properties

103.1 References from Toxicology Branch

See previous Reviews

The following studies were deferred to Tox. Branch for review and Validation. (Results still pending).

Acc. # 245704

Study #10 - Bratt, H. & Hudson, P. "Brodifacoum: Adsorption, Excretion, and tissue retention in the Rat," ICI Central Toxicology Laboratory Report No. CTL/P/462 [June, 1979]

#12 - Ussary, J.P., "An HPLC Method for the Determination of Broadifacoum in Animal Tissue," ICI Americas Inc., Goldsboro Residue Analytical Method No. GRAM-2/1

#13 - Koubek, K.G., "Brodifacoum Residues in Rodents, Pheasants and Ground Rat Tissue", ICI Americas Inc., Report No. TMU0545/B [December, 1980].

#19 - Parkinson, G.R., "WBA 8119: Acute Oral Toxicity", ICI Central Toxicology Report No. CTL/P/216.

#20 - Ross, D.B., and Roberts, N.L., "The Oral Toxicity of WB 8119 to the Domestic Pig", Huntingdon Research Center Report No. SRX 2/7670

Study #21 - Parkinson, G. R. "Acute Oral Toxicity to Sheep",
ICI Central Toxicology Laboratory Report No.
CTL/P/259.

Study #23 - Dickie, B.C. and Balk, M.W. "Palatability of a
Rodenticide Base in Dogs", Raltech Scientific
Services Study No. 80527

Study #24 - Morris, K.D. "Talon, Secondary Toxicity of Brodifacoum
to Dogs (Beagles), North Carolina, ICI Americas Inc.
Report No. TMUD 1977/B.

The following 26 studies in Acc. #245704 were reviewed. Of these
twenty six the following numbered studies were deferred to other
Branches of HED and OPP for validation: Studies # 8, 9, 10, 12, 13,
19, 20, 21, 23, 24. EEB did a cursive review of these studies
but will have to await the validation by other Branches in HED
and OPP before completing a Hazard Assessment.

1. Ross, D. B., Roberts, N. L. and Cameron, D. M. "The Acute Oral Toxicity
(LD50) of PP581 to the Mallard Duck" Huntingdon Research Center Report
No. ICI 122WL/78507 [June, 1978].
2. Fink, R. "8-Day Dietary LC50 - Mallard Duck. PP581 Technical", Wildlife
International Ltd. Report Project No. 123-115 [October, 1976].
3. Fink, R. "8-Day Dietary LC50 - Bobwhite Quail. PP581 Technical",
Wildlife International Ltd. Report Project No. 123-114 [October, 1976].
4. Fink, R. "8-Day Dietary LC50 - Mallard Ducks. Technical Brodifacoum",
Wildlife International Ltd. Report Project No. 124-124 [August, 1978].
5. Fink, R. "40-Day Dietary LC50 - Mallard Duck. Technical Brodifacoum",
Wildlife International Ltd. Report Project No. 123-128 [December, 1978].
6. Fink, R. "40-Day Dietary LC50 - Bobwhite Quail.
Technical Brodifacoum", Wildlife International Ltd.
Report Project No. 123-127 [December, 1978].
7. Fink, R. "40-Day Dietary LC50 - Laughing Gull. Technical Brodifacoum",
Wildlife International Ltd. Report Project No. 123-125 [February, 1979].
8. Ross, D. B., Roberts, N. L., and Phillips, C. N. K. "Assessment of the
Palatability of "TALON" Pellets Containing 0.005% (50 ppm) Brodifacoum to
the Bobwhite Quail", Huntingdon Research Center Report No. ICI 296
WL/79864 [November, 1979].
9. Ross, D. B., Roberts, N. L., and Phillips, C. N. K. "Assessment of the
Palatability of "TALON" Pellets Containing 0.005% (50 ppm) Brodifacoum
to the Ring-Necked Pheasant", Huntingdon Research Center Report No.
ICI 276 WL/781181 [July, 1979].

10. Bratt, H., and Hudson, P., "Brodifacoum:" Adsorption, Excretion and Tissue Retention in the Rat", ICI Central Toxicology Laboratory Report No. CTL/P/462 [June, 1979].
11. Fink, R., "40-Day Dietary LC50-Laughing Gull. Masticated Rodent Tissue Containing PP581", Wildlife International Ltd. Report Project No. 123-126 [May, 1979].
12. Ussary, J. P., "An HPLC Method for the Determination of Brodifacoum in Animal Tissue", ICI Americas Inc., Goldsboro Residue Analytical Method No. GRAM-2/I.
13. Koubek, K. G., "Brodifacoum Residues in Rodents, Pheasants and Ground Rat Tissue", ICI Americas Inc., Report No. TMU0545/B [December, 1980].
14. Jaber, M., "A Literature Search of the Dietary Habits of Avian Predators", ICI Americas Inc., Report No. TMUE0001 [April, 1980].
15. Hegdal, P. L. and Blaskiewicz, R. W., "Hazards to Barn Owls Associated with the Use of TALON Rodenticide for Controlling Rats and House Mice" Pre-Publication report to ICI Americas from U.S. Fish and Wildlife Service - Denver.
16. Mendenhall, V. M., and Pank, L. F., "Secondary Poisoning of Owls by Anticoagulant Rodenticides", Wildlife Society Bulletin 8 (4), 311-315 [1980].
17. Marsh, R. E., and Howard, W. E. "Secondary Toxicity Hazard Tests of Brodifacoum to Raptors", (Preliminary Report of University of California, Davis) [April, 1978].
18. Savarie, P. J. and LaVoie, G. K., "Secondary Toxicity Hazards of the Anticoagulant Brodifacoum to American Kestrels (Falco sparverius)", "Pre-publication report to ICI Americas from the U. S. Fish and Wildlife Service - Denver.
19. Parkinson, G. R., "WBA 8119: Acute Oral Toxicity", ICI Central Toxicology Report No. CTL/P/216.
20. Ross, D. B., and Roberts, N. L., "The Oral Toxicity of WB 8119 to the Domestic Pig", Huntingdon Research Center Report No. SRX 2/7670.
21. Parkinson, G. R., "Acute Oral Toxicity to Sheep", ICI Central Toxicology Laboratory Report No. CTL/P/259.
22. Ringer, R.K. and Aulerich, R. J. "Determination of Oral LD50 of Brodifacoum for Mink", Michigan State University Report.

23. Dickie, B. C. and Balk, M. W. "Palatability of a Rodenticide Base in Dogs", Raltech Scientific Services Study No. 80527.
24. Morris, K. D. "TALON: Secondary Toxicity of Brodifacoum to Dogs (Beagles) (North Carolina)", ICI Americas Inc. Report No. TMUD1977/B.
25. Morris, K. D. "TALON: Secondary Toxicity of Brodifacoum to Foxes (North Carolina)", ICI Americas Inc. Report No. TMUD1998/B.
26. Pank, L. F. and Hirata, D. N. "Primary and Secondary Toxicity of Anticoagulant Rodenticides", U. S. Fish and Wildlife Services, Wildlife Damage Research Station, Hilo, Hawaii. July 1976.

The following are the outcomes of the reviews of the remaining 26 studies.

<u>Study number</u>	<u>Category</u>	<u>Rationale</u>
1. - 6	-NA-	Re-Review of these studies was done. Previously validation categories still stand.
7 & 11	Invalid	Supplemental feed Contained antidotal Medication. Material may be even more toxic than shown.
14.	Supplemental	An incomplete but interesting literature search. Adds negative input into test 15.
15.	Supplemental	Exposure of owls to target prey may not have been carried out in a worst case situation.
16.	-NA-	This test was designed to show an affect/no affect testing of secondary hazard to raptors. There is a secondary hazard associated with brodifacoum.

17.

-NA-

Red tailed and Red shouldered hawks died during brodifacoum testing. Golden eagles survived. Research indicates that the report may be biased by the use of supplemental feed which contained vitamin k.

18.

-NA-

Vitamin K complex was present in the supplemental feed whereby the results could of been biased.

22.

Invalid

Use of additional amounts of a Vitamin K would bias the results (e.g. use of an antidote in testing).

25.

Supplemental

Indicates a secondary Hazard to foxes.

26.

Supplemental

Indicate Secondary Hazard to mammals and Raptors.

104 Hazard Assessment

See previous Reviews

Our concerns for secondary and primary hazards to mammalian and avian species still exist. The present data package did not contain sufficient data to remove the previous request for more data.

107. Conclusions

EEB cannot concur with the label change for Talon G pellets. The need for secondary hazard and primary hazard studies with this product on mammalian and avian species still exist. We further re-iterate that brodifacoum exceeds the RPAR criteria as stated under Paragraph 162.11, (2)(6)(i) of regulation for enforcement of FIFRA as Amended, when considered for outdoor use.

6

Russel T. Farringer, III

Russel T. Farringer, III
Wildlife Biologist
Ecological Effects Branch/HED

Date: 11/20/81

Raymond W. Matheny
Raymond Matheny
Head, Review Section 1
Ecological Effects Branch/HED

Date: 11/20/81

Raymond W. Matheny
For Clayton Bushong
Branch Chief
Ecological Effects Branch/HED

Date: 11/20/81



Proposed Amended Label

July 22, 1981

TALON-G Rodenticide Bait Pack (Mini-Pellets)
EPA Reg. No. 10182-40

ICI requests that the attached registered label be amended to read as follows:

* * *

FOR EFFECTIVE CONTROL OF COMMENSAL MICE AND RATS

* * *

DIRECTIONS FOR USE

* * *

USE RESTRICTIONS: For control of Norway Rats, Roof rats and House mice in and around homes, industrial, commercial, public and agricultural buildings. TALON may also be used inside transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Treated baits must be placed in tamper-proof bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

* * *

JMW/bmw/V/M/B-19

Attachment

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Talomin-GTM

RODENTICIDE PELLETS

For Effective Urban Rodent Control

STORAGE: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

DISPOSAL: Dead animals and bait that cannot be used should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies. Dispose of container in an incinerator, or landfill approved for pesticide containers or bury in a safe place. Consult Federal, State or local disposal authorities or approved alternate procedures such as limited incineration.

USE RESTRICTIONS: For control of Norway rats, Roof rats and House mice in and around the periphery of homes, industrial, commercial, and public buildings located in urban areas. May also be used in alleys located in urban areas. Do not use in sewers or public parks. Treated baits must be placed in tamper-proof bait boxes or in locations not accessible to children, pets, domestic animals or wildlife. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not bait within one mile radius of nesting sites being used by raptors. Consult State Wildlife officials, local bird experts and U.S. Fish and Wildlife Service personnel to determine locations of such nesting sites.

SELECTION OF TREATMENT AREAS: Determine areas where rats and/or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places between floors and walls or in locations where rodents or their signs have been observed. Remove as much food as possible.

Apply 4 to 16 ounces of bait (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for 10 days or until signs of rat activity cease.

Apply 1/4 to 1/2 ounce of bait at intervals of 8 to 12 feet per placement. Larger placements (up to 2 ounces) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for 15 days or until signs of mouse activity cease.

Replace contaminated or spoiled bait immediately. Collect and dispose of all dead animals and unconsumed bait according to "Disposal" paragraph. To prevent reinfestation, eliminate food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of reinfestation is present, establish permanent bait stations and replenish bait as needed.

Kills warfarin-resistant Norway Rats and house mice.

Rodents may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

Active Ingredient:

Brodifacoum-

3-[3-(4-bromo-1-biphenyl)-4-yl]-

1,2,3,4-tetrahydro-1-naphthalenyl]-4-

hydroxy-2H-1-benzopyran-2-one

Inert Ingredients

0.005%

99.995%

100.000%

Total

May Be Harmful or Fatal if Swallowed
Read Additional Precautionary Statements
on Side Panel



ICI Americas Inc.

Wilmington, Delaware 19897

EPA Reg. No. 10182-43
EPA Est. No. 523-IL-1
Net Contents: 45 lb (20.4 kg)

Batch Number:

MAY BE HARMFUL OR FATAL IF SWALLOWED. KEEP AWAY FROM HUMANS, DOMESTIC ANIMALS, AND PETS. WASH HANDS AFTER HANDLING BAIT. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE.

For 24-hour emergency assistance call 302/575-3000.

In case of significant spill, call CHEMTREC 800/424-9300.

This product may reduce the clotting ability of the blood and cause hemorrhaging. If this occurs, intravenous and oral administration of vitamin K₁ combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bis(hydroxycoumarin). Vitamin K₁ is antidotal at doses of 10 to 20 mg (not mg/kg) and should be given and repeated as necessary (based on monitoring of prothrombin times).

This product is toxic to fish and wildlife. Use with caution in areas frequented by wildlife. Raptors, predators and domestic animals that eat rodents may be killed by feeding on poisoned rodents. Keep out of lakes, ponds, or streams. Do not use this product in public parks.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller and Buyer and User assumes the risk of any such use. SELLER DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

ACD 790-96R1 6/81 5M

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use
in
sale

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