DATE: September 11, 1980

SUBJECT: EPA Registration No. 4816-549 ROACH & ANT SPRAY
Caswell #508

FROM: Cheryl Ann Peterson
IRB/TSS

TO: Mr. Jay Ellenberger
Product Manager (12)

Registrant: Fairfield American Corporation
3932 Salt Road
Medina, NY 14103

Active Ingredients:
Baygon [2-(1-methylethoxy)phenol methylcarbamate]........1%
Petroleum Distillate........................................84%

Inert Ingredients............................................15%

Background:
This previously registered (last accepted label 10-19-79) product is intended for household use against roaches, ants, ticks, fleas, etc. The company is submitting additional data in support of conditional registration in the form of acute dermal, primary eye irritation, acute oral, acute inhalation and primary dermal irritation studies.

Recommendations:

1. The appropriate signal word is WARNING, as indicated by the eye irritation study. Therefore, it is suggested that, at the next label reprinting, the revisions indicated below be incorporated.

2. The acute inhalation data has been classified Core Supplementary Data (see individual test review for verification).

3. The acute oral, acute dermal, primary eye irritation and skin irritation studies are acceptable.

Labeling:

1. The appropriate signal word is WARNING, as indicated by the eye irritation test.
2. There should be something similar to the following under the subheading "HAZARDS TO HUMANS & DOMESTIC ANIMALS:

WARNING: Causes eye irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid breathing spray mist and provide adequate ventilation of area being treated. Wash thoroughly after using. Avoid contamination of food, utensils and food preparation areas.

STATEMENT OF PRACTICAL TREATMENT:

If in eyes: Flush with plenty of water. Get medical attention.
If swallowed: Drink glass of water. Do NOT induce vomiting, get medical attention.

Note to Physician: This product contains a cholinesterase inhibitor. Should signs of cholinesterase inhibition appear, atropine sulfate is anticoital.

Review:

The following studies were performed by Cosmopolitan Safety Evaluation (CSE), Inc., 76 Fourth Street, Somerville, N.J. 08876 on material identified as Baygon 1% Roach and Ant Spray for Fairfield American Corporation. They were received by EPA on 6-11-80, and are in Acc. No. 242737.

1. Acute Dermal LD50 - Rabbit. Dated: 5-11-80

Procedure: 5M, 5F albino NZ rabbits received 24-hour, occluded exposure to 2.0 g/kg test material on shaved skin. There was a 14-day observation period, with survivor sacrifice and necropsy.

Results: LD50 2.0 g/kg. 1 Male die on Day 1 (no explanation given). 9/10 animals showed minor edema and erythema through Day 3 with clearing by Day 7. 1 M gained weight during the observation period, while the rest of the animals lost weight.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. III


Procedure: 9 NZ albino rabbits received 0.1 ml test material. 3/9 animals neo eyes washed starting 20 sec. after instillation with water for one minute. Observations were made at 24, 48, 72 hours and Days 4 and 7.

Results: 2/6 unwashed eyes showed minor corneal opacity at 48 hours with
clearing in 1/6 by 72 hours and 1/6 by 4 days. 2/3 washed eyes showed
minor corneal opacity at 24 hours with clearing by 48 hours.

Study Classification: Core Guideline Data.

Product Classification: Tox. Cat. II.


Procedure: 5 albino rats (unspecified strain) orally received 2.5,
3.2, 3.6 g/kg. 2 rats received 3.8 and 4.0 g/kg. Survived 13, 1.6,
2.0, 2.5 and 3.1 g/kg. There was a 14-day observation period with
survivor sacrifice and necropsy.

Results: LD₅₀ for M=3.75 g/kg (95% conf. lim. 3.50-4.01). LD₅₀ for
F=3.20 g/kg (95% conf. lim. 2.01-5.09). 2/5 M died Days 2 & 5 at 3.2
g/kg, 3/10 M died Days 1, 6 & 7 at 3.6 g/kg, 1/5 M died Day 1 at 3.8
g/kg and 6/10 M died Days 1-3 at 4.0 g/kg. 1/5 F died Day 1 at 1.3 g/kg,
2/5 F died Days 1 & 2 at 1.6 g/kg, 1/5 F died Day 1 at 2.0 g/kg, 2/5 F
died Day 1 at 2.5 g/kg, 3/5 F died Days 1 & 2 at 3.1 g/kg. Clinical
signs included ataxia, tremors and hematuria which usually cleared by 24
hrs after dosing. Surviving animals gained weight during the observation
period. Necropsy showed yellow contents in stomach and hematuria.

Study Classification: Core Minimum Data (Rat strain should be specified).

Product Classification: Tox. Cat. III.

4. Acute Inhalation LC₅₀ - Rat. Date: May 22, 1980

Procedure: 5M, 5F albino rats (unspecified strain) were exposed to a
nominal concentration of greater than 5.0 mg/l for 4 hrs. A raised floor
supported individual wire cages in the plexiglass test chamber which had
a portal on top and an exit portal near the bottom of the cage. Airflow
was maintained by a compressor & pressure regulator. Test article issued
from a continuous flow nebulizer. 7.86 mg/l of test article was released during the
4 hr. exposure. Air was supplied at a measured flow rate and pressure to the
generator. There was a 14-day observation period with survivor sacrifice
and necropsy. A control group of 10 animals was also run.

Results: No mortalities. No clinical signs. Necropsy revealed nothing
unusual. Weight gains were similar among test and control animals, all
showed net weight gain.

Study Classification: Core Supplementary Data. (Actual chamber
concentration measurements should be taken to determine if chamber
concentration is constant during exposure period.)

Procedure: 6 young, albino NZ rabbits received 24-hr, occluded exposure to 0.5 ml of test article applied at 2 intact and 2 abraded skin sites. Observations were made at 24 hrs and 72 hrs.

Results: Primary Irritation Score is 4.19. 6/6 animals showed minor edema at 24 hrs with clearing in 4/6 by 72 hrs. Erythema was present in all animals through 72 hrs.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. III.
CODE 723.30
NAUGON & AMP; AMP; TIRAM

DIRECTIONS FOR USE

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

STORAGE AND DISPOSAL
Do not reuse empty container. Wrap container and put in trash collection.

FOR HOUSEHOLD USE ONLY:
Roach & Ant Spray (containing BAYGN) is a highly effective new formulation which provides rapid kill of such crawling insects as those listed below, including insects resistant to certain chlorinated hydrocarbon and phosphate insecticides.

Ants, Cockroaches, Spiders and other Crawling Insects in and around homes
Insect Killing Power Lasts for up to Two Weeks
Spray only on surfaces - do not use as a space spray

ACTIVE INGREDIENTS:
82-(l-methyleneoxy)phenol methylcarbamate... 1%
Petroleum Distillate.......................... 84%
INERT INGREDIENTS.................................................. 15%
# U.S. Patent No. 3,111,539
100%

BAYGN is a registered trademark of the Parent Company of Farbenfabriken Bayer GmbH, Leverkusen.

Keep Out Of Reach Of Children
CAUTION
TO PHYSICIAN: Atropine sulfate is antitodal.
See rear panel for additional precautions.

EPA Reg. No. 4016-549
EPA Est. No. 279-MT-1

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION
Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist and provide adequate ventilation of area being treated. Contact with skin, eyes or clothing should be avoided. Wash thoroughly after using. Avoid contamination of food, utensils and food preparation areas. Should poisoning occur, get prompt medical aid.

ENVIRONMENTAL HAZARDS
This product is toxic to fish and wildlife. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL OR CHEMICAL HAZARDS
Do not use or store near heat or open flame.

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SEE REVERSE SIDE