1-14-88

To: George LaRocca
Program Manager (15)
IRB/RD (TS-767C

From: Van M. Seabaugh
TSS/IRB/RD (TS-767C) VMS 1-14-88

Subject: EPA Registration No. 4833-GEG; Record No.: 207331; Action Code 161; Accession No.: 403973-01, 4-3630-1, 403630-02, 403630-03. RAID Ant & Roach Killer 6.

Registrant:

S.C. Johnson & Son, Inc.
Racine, WI 53403-5011

Confidential
Formulation
(2-27-87) :

Ingredient(s)	% by wt.
Permethrin [redacted]	.22
Pyrethrins [redacted]	.37
Piperonyl Butoxide	.50
[redacted]	
	100.00

INERT INGREDIENT INFORMATION IS NOT INCLUDED
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Summary:

I. Eye Irritation Testing (§81-4)

Classification: supplementary. We want the pressurized aerosol tested.

II. Oral Toxicity (§81-1)

Classification: core - minimum (limit test); toxicity category IV.

III. Dermal Toxicity (§81-2)

Classification: core - minimum (limit test); toxicity category III.

IV. Dermal Irritation (§81-5)

Classification: core - guideline; toxicity category IV.

V. Acute Inhalation (§81-3)

1/6

Summary Continued

The registrant stated that acute inhalation data are "not needed for this product based on the particle size and use pattern." We disagree, and want the information submitted.

VI. Dermal Sensitization (§81-6)

This information needs to be submitted.

VII. Labeling

The submitted label cannot be fully commented upon until we receive the requested toxicity information.

I. Study Type: Eye Irritation Testing (§81-4)

Record No.: 403973-01

Testing Facility: Food & Drug Research Laboratories, Inc. (FDRL)
Route 17c, P.O. Box 107
Waverly, N.Y. 14892-0107

FDRL Study No.: Lab. Project ID 5966D84, document no. 5966D84-3T.

Report Date: 3-06-87

Author: Bernadette Busch

Title Of Report: Primary Eye Irritation Study

A. Materials

1. Test Material: 5966D84-a (Sponsor Number); 87-0070 (FDRL No.).

2. Test Animals: Species: rabbits. Strain: New Zealand. Weight: 2-3 kg. Source: Ace Animals Inc., Boyertown, Pa.

B. Study Design

Six young adult rabbits were tested. One tenth ml was instilled into the conjunctival sac of each test eye. The eye lids were then held together for one second and released. The contralateral eye of each rabbit served as a control. Sodium fluorescein was used for prescreening. The eyes were evaluated at 1, 24, 48, and 72 hours.

C. Quality Assurance

Stated and signed as being in compliance with EPA's GLPs.

D. Results:

	Number "positive"/number tested at Hours			
	1	24	48	72
Cornea	0/6	0/6	0/6	0/6
Iris	0/6	0/6	0/6	0/6
Conj.				
Redness	0/6	0/6	0/6	0/6
Chemosis	0/6	0/6	0/6	0/6
Discharge	0/6	0/6	0/6	0/6

Conclusion: Classification: Supplementary. "To test a substance contained in a pressurized aerosol container the eye should be held open and the substance administered in a single burst of about one second from a distance of 10 cm directly in front of the eye. The dose may be estimated by weighing the container before and after use [Pesticide Assessment Guidelines Subdivision F Hazard Evaluation: Human And Domestic Animals, Revised Edition (November 1984)]."

II. Study Type: Oral Toxicity Testing (§81-1)

Record No.: 403630-03

Testing Facility: Food & Drug Research Laboratories, Inc. (FDRL)
Route 17c, P.O. Box 107
Waverly, N.Y. 14892-0107

FDRL Study No.: Lab. Project ID 5966D84, document no. 5966D84-1T.

Report Date: 4-09-87

Author: Elizabeth Reagan

Title Of Report: Raid Ant & Roach Killer 6
Acute Oral Toxicity

A. Materials

INERT INGREDIENT INFORMATION IS NOT INCLUDED

1. Test Material: 5966D84-a (Less propellent). According to Robert Yocum (S.C. Johnson & Son, Inc.), [redacted] was the only ingredient omitted.

2. Test Animals: Species: rats. Strain: Sprague-Dawley. Sex: Male and females. Weight: 222-259 g. Source: Charles River Breeding Laboratories, Inc., Wilmington, MA.

B. Study Design

A limit test was conducted using 5 male and 5 females. The rats were administered the test material by gavage at a dose level of 5 g/kg. Observation times included three times on day of dosing, and twice daily thereafter for 14 days. Body weights were determined on days 1, 8, and 15. Gross necropsy was conducted on all animals.

C. Quality Assurance

Stated and signed as being conducted according to EPA's GLPs.

D. Results

The mortality ratio (0/10) was zero deaths out of the ten rats tested (14 day observation). Reported observations included the following: diarrhea, decreased activity, labored breathing, salvation, apparent urinary incontinence, sores and/or hair loss at the base of the tail or rectum. The mean body weights indicated that the rats gained weight during the test. No control data were provided.

Classification: core-minimum (limit test); toxicity category IV.

III. Study Type: Acute Dermal Toxicity

Record No.: 403630-02

Testing Facility: Food & Drug Research Laboratories, Inc. (FDRL)
Route 17c, P.O. Box 107
Waverly, N.Y. 14892-0107

FDRL Study No.: Lab. Project ID 5966D84, document no. 5966D84-2T.

Report Date: 3-17-87

Author: Bernadette Busch

Title Of Report: Acute Dermal Toxicity Study Of 5966D84-a, Less propellent (2-17-87) In New Zealand White Rabbits.

A. Materials

1. Test Material: 5966D84-a (less propellent); FDRL No. 9384A.

2. Test Animals: Species: rabbits. Strain: New Zealand. Weight: 2-3 kg. Source: Ace Animals Inc., Boyertown, Pa.

B. Study Design

The test material (2 g/kg) was applied for 24 hours to the non-abraded backs of rabbits (5 males and 5 females) clipped free of hair. "The test sites were wrapped with occlusive binders consisting of a layer of plastic wrap and stockinette sleeve held in place with tape. The binders were removed 24 hour post-exposure administration and the exposure sites gently wiped with gauze to remove as much non-absorbed test article as possible." Animals were observed for mortality and pharmacotoxic signs at dosing and twice daily thereafter. The observation period was for 14 days. Body weights were recorded on days 1, 8, and 15. Gross necropsy was conducted on all animals.

C. Quality Assurance

A statement was made and signed that the test was conducted according to EPA's GLPs.

D. Results

None of the 10 rabbits (5 males and 5 females) died during the 14 day observation period after dosing (2 g/kg). No lesions or abnormalities were seen upon gross necropsy. Weight gain was seen in all animals at the end of the study. One male had soft stools and diarrhea on days 5-7 post dosing. The estimated LD50 is greater than 2 g/kg.

Classification: Core - minimum (limit test).
Toxicity category III.

IV. Study Type: Dermal Irritation (§81-5)

Record No.: 403630-01'

Testing Facility: Food & Drug Research Laboratories, Inc. (FDRL)
Route 17c, P.O. Box 107
Waverly, N.Y. 14892-0107

FDRL Study No.: Lab. Project ID 5966D84, document no. 5966D84-4T.

Report Date: 3-20-87

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Author: Bernadette Busch

Title Of Report: RAID Ant & Roach Killer 6
Primary Dermal Irritation Study
Of 5966D84-a (less propellent)

A. Materials

1. Test Material: 5966D84-a. FDRL Study No. 9384A.
2. Test Animals: Species: rabbits. Strain: New Zealand. Weight: 2-3 kg. Source: Sgarlat's Rabbitry, Harveys Lake, Pa.

B. Study Design

Six young adult rabbits were tested with 5966D84-a (less propellent). Each rabbit was adminstered 0.5 ml of the test material for four hours to two non-abraded test sites (clipped free of hair). "The test sites were wrapped with semi-occlusively binders consisting of one-inch square gauze patch and Micropore® tape immediately after dosing. The animals wore "collars." The binders were removed four hours postdose administration and the exposure sites gently wiped with gauze to remove as much non-absorbed test article as possible." Dermal erythema and edema were recorded at: a) 4.5, 28, 52, and 76 hours. b) 4, 7, 10, and 14 days.

C. Quality Assurance

A statement was made and signed that the study was conducted in accordance with EPA's GLPs.

D. Results

A primary irritation index (PII = 1.42) was calculated for the readings taken at 4.5, 28, 52, and 76 hours.

Classification: core - guideline; toxicity category IV.

V. Study Type: Acute Inhalation (§81-3)

The registrant stated that the acute inhalation test was "not needed for this product based on the particle size and use pattern." We disagree, and want the information submitted.