118301

CASWELL FILE
008010

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

MRID 411164-01

JUN 26 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fenvalerate/Esfenvalerate - Submission of a Skin Sensory Stimulation Study on Several End Use Products (EPA Registration No. 352-502)

Tox Chem. Nos: 77A/268J/2AA
Project No: 9-1646
Record No: 246788

FROM: William B. Greear, M.P.H. William B. Greear 6/19/90
Review Section II, Toxicology Branch I
Health Effects Division (H7509C)

TO: Adam Heyward/George LaRocca, PM Team # 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Marion P. Copley, D.V.M., Section Head Marion Copley 6/21/90
Review Section II, Toxicology Branch I
Health Effects Division (H7505C)

Conclusions

The study is Core-Supplementary. The information provided indicates that varying the formulation components of Asana 0.66 EC can influence the skin stimulation properties of Asana 0.66 EC.

(1)

Reviewed by: William B. Greear, M.P.H. William B. Greear 6/19/90
Review Section II, Toxicology Branch I
(H7509C)

Secondary Reviewer: Marion P. Copley, D.V.M. Marion Copley 6/21/90
Review Section II, Toxicology Branch I
(H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Skin Sensory Stimulation

TOX CHEM Nos.: 77A
268J
2AA

MRID No.: 411164-01

Test Materials:
1. Pydrin 2.4 EC
2. Payoff 2.5 EC
3. Asana 1.9 EC - formulation 1
   - formulation 2
   - formulation 3

4. Asana 0.66 EC - formulation 1
   - formulation 2
   - formulation 3

5. Asana 1.28 EC

Synonyms: See Attachment # 1 for a description of each test substance (includes purity, color, CAS No.). See Table 1 for a description of each formulation tested.

Sponsor: Du Pont

Testing Facility: Du Pont
Haskell Laboratory for Toxicology and
Industrial Medicine
Newark, DE 19714

Title of Report: Skin Sensory Stimulation Elicited by Various Pyrethroid Formulations in Guinea Pigs

Author: L. A. Malley

Study No: Medical Research No. 4581-536, -522, -553
Haskell Laboratory Report No. 308-88

Report Issued: May 5, 1989

Classification: Supplementary

(2)

Conclusions: Varying the formulation components of Asana 0.66 EC can influence the skin stimulation properties of Asana 0.66 EC.

Materials and Methods:

Young adult male Duncan Hartley albino guinea pigs were obtained from Charles River Breeding Laboratories, Stone Ridge, NY and were allowed to acclimate to laboratory conditions for approximately 1 week. The animals were individually housed in suspended, stainless steel, wire-mesh cages in rooms with a temperature of 23 ± 2° C, relative humidity of 50 ± 10% and a 12-hour on/ 12-hour off light cycle. Purina Certified Guinea Pig Chow # 5026 and water were available ad libitum except for the 4-5 hour observation period on the day of the test. Approximately 24-72 hours prior to study initiation, the hair on the back and trunk of each quinea pig was clipped. A depilatory lotion was then used for approximately 10-15 minutes. The test areas were washed with water and then dried with a paper towel. On the day of treatment, 0.1 ml of the test material was placed on the flank (a 5 X 5 cm^2 area) on the quinea pig. Approximately, 0.1 ml of a second test material was placed on the opposite flank. The guinea pigs were then observed for scratching, licking or biting of the test sites for 5 minute intervals after 10, 25, 40, 55, 115, 175 and 235 minutes. The scratching, licking, biting behavior was quantitated by counting the number of times the animal licked, bit or scratched the test site. The responses from each interval were added to obtain a cumulative response score for each animal. When 2 test substances were simultaneously applied, both a cumulative score and a percentage were calculated for each test substance. The percentage was calculated by dividing the cumulative score for each test substance applied by the sum of the scores for both test substances and multiplying by 100. Cumulative scores for each pair of pyrethroids applied were analyzed using a student's t-test. Significance was determined at the alpha = 0.05 level. A number of comparisons were tested with various formulations. In addition, comparisons were made testing formulations at various concentrations. The comparison tests are indicated in the table below. Each group consisted of 4 male guinea pigs.

Test No.	Test Substance	Formulation Concentration (%)	Active Ingredient (%)	Active Isomer (%)
1	Pydrin 2.4 EC	2.1	0.69	0.15
	Payoff 2.5 EC	0.8	0.27	0.07
2	Pydrin 2.4 EC	0.52	0.17	0.004
	Payoff 2.5 EC	0.2	0.07	0.002
3	Pydrin 2.4 EC	0.52		
	Asana 1.9 EC	0.2	0.06	0.05
4	Pydrin 2.4 EC	0.52	0.17	0.004
	Asana 1.9 EC*	0.2	0.06	0.05

* - "Different solvent system"

5	Pydrin 2.4 EC	0.52	0.17	0.04
	Asana 1.9 EC	0.16	0.05	0.04
6	Pydrin 2.4 EC	0.053	0.017	0.004
	Asana 0.66 EC	0.058	0.006	0.005
7	Pydrin 2.4 EC	0.52	0.17	0.04
	Asana 0.66 EC	0.58	0.06	0.05
8	Pydrin 2.4 EC	1.05	0.35	0.08

	Asana 0.66 EC	1.15	0.12	0.10
9	Pydrin 2.4 EC	0.52	0.17	0.04
	Asana 0.66 EC **	0.58	0.06	0.05
10	Pydrin 2.4 EC	0.52	0.17	0.04
	Asana 1.28 EC	0.30	0.06	0.05
11	Asana 1.9 EC	0.02	0.006	0.005
	Asana 0.66 EC	0.058	0.006	0.005

**-Different formulation lacks [redacted]

12	Asana 1.9 EC	0.2	0.06	0.05
	Asana 0.66 EC (Trial #1)	0.58	0.06	0.05
13	Asana 1.9 EC	0.2	0.06	0.05
	Asana 0.66 EC (Trial #2)	0.58	0.06	0.05
14	Asana 0.66 EC	0.06		
	Asana 0.66 EC***	0.06		
15	Asana 0.66 EC	0.58	0.06	0.05
	Asana 0.66 EC***	0.58	0.06	0.05

(5)

16	Asana 1.9 EC	0.02	0.006	0.005
	Payoff 2.5 EC	0.02	0.007	0.0002
17	Asana 1.9 EC	0.2	0.06	0.05
	Payoff 2.0 EC	0.2	0.07	0.0002

***-Solvent only formulation

Results

Summaries of the results of the tests can be found in Tables 4-10 (attached).

Comparison of Pydrin 2.4 EC to Payoff 2.5 EC

At field-use dilutions of 2.1% Pydrin and 0.8% Payoff, no differences in skin sensory stimulation were discerned. However, at 1/4 of field-use dilutions (0.52% Pydrin, 0.2% Payoff), Payoff produced the greatest stimulation (see Table 4).

Comparison of Pydrin 2.4 EC to Two Formulations of Asana 1.9 EC

When Pydrin and Asana were tested at 1/4 field-use dilutions of 0.52% and 0.2%, respectively, Asana produced the greatest simulation. When Pydrin and Asana were tested at concentrations at which they both contained equivalent amount of the active isomer (0.52% and 0.16%, respectively), Asana produced the greatest stimulation. A second Asana formulation was tested that contained [redacted] At a concentration of 0.2% the second Asana formulation produced more stimulation than the Pydrin formulation at a concentration of 0.52%. It was concluded that the difference in the degree of stimulation between Pydrin and Asana could not be related to the active isomer concentration or to a change in the solvent system (not described) that contained [redacted] (see Table 5).

Comparison of Pydrin 2.4 EC to Two Formulations of Asana 0.66 EC

Asana 0.66 EC, at concentrations of 0.058% and 0.58% (1/4 field-use dilution), and Pydrin at concentrations of 0.053% and 0.52% were tested. The skin sensory stimulation were comparable among the 4 test groups. However, Asana at a concentration of

1.15% caused greater stimulation than Pydrin at a concentration of 1.05%. A second formulation of Asana that did not contain the [redacted] was tested at 0.58% and compared to Pydrin at a concentration of 0.53%. The second Asana formulation produced greater stimulation. It was concluded that at concentrations greater than 1/4 field-use dilution, Asana produced greater stimulation than Pydrin (see Table 6).

Comparison of Pydrin 2.4 EC to Asana 1.28 EC

The field-use dilution of Pydrin (0.52% and 1/4 field-use dilution of Asana (0.30%) were tested and found to be comparable (see Table 7).

Comparison of Asana 1.9 to Asana 0.66 EC

Asana 1.9 EC at concentrations of 0.02 or 0.2% and Asana 0.66 EC at concentrations of 0.058 and 0.58% were tested. Asana 1.9 EC at a concentration of 0.02% caused greater skin sensory stimulation than Asana 0.66 EC at a concentration of 0.058%. However, at higher concentrations of 0.58% and 0.2%, respectively, Asana 0.66 EC produced more skin sensory stimulation than Asana 1.9 EC (see Table 8).

Comparison of Two Asana 0.66 EC formulations

Concentrations of 0.06% and 0.58% of Asana 0.66 EC and concentrations of 0.067% and 0.58% Asana 0.66 EC (solvent only) were tested. The solvent only formulation was somewhat (64%) less stimulating than Asana 0.66 EC at a concentration of 0.58% and 42% less stimulating at a concentration of 0.06% (see Table 9).

Comparison of Asana 1.9 EC to Payoff 2.5 EC

Asana 1.9 EC and Payoff 2.5 EC were both tested at concentrations of 0.02% or 0.2%. At both concentrations, the skin sensory stimulation evoked by Payoff 2.5 EC was quite similar to Asana 1.9 EC (see Table 10).

Summary

The Various pyrethroid formulations tested varied with respect to the concentration of technical Asana, percentage of [redacted] percentage of [redacted] percentage and type of [redacted] and type of solvent. Payoff 2.5 EC, two formulations of Asana 1.9 EC and Asana 1.28 EC elicited more skin sensory stimulation than Pydrin 2.4 EC. Concentrations of 0.58% or less of Asana 0.66 EC and Pydrin 2.4 EC caused equivalent stimulation. However, at higher concentrations Asana 0.66 EC produced more stimulation than Pydrin 2.4 EC. Similarly, at concentrations of 0.058% Asana 0.66 was less stimulating than

Asana 1.9 EC; but, was more stimulating at higher concentrations. The degree of skin sensory stimulation was similar for Payoff 2.5 EC and Asana 0.66 EC. [The data indicate that altering formulation components can influence the skin sensory effects of Asana 0.66 EC.]

(8)

Esfenvalerate toxicology review

Page _____ is not included in this copy.

Pages 9 through 27 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

X FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.