SHORT-TERM STUDY PROTOCOL SHEET

MR NUMBER: MR-3540-001
HASKELL NUMBER: 13,257
NAME & SYNONYM: Paint, Dulux Enamel

TYPE TEST: SK-MISC - SK-ABS RABBIT
DOSAGE LEVELS: 1 ml with 2.0% lead each day / 10 days.
PROPOSED STARTING DATE: 10/8/79
PROPOSED COMPLETION DATE: —
DISPOSAL OF WASTE MATERIALS: Shouldn't be any.

SPECIAL SAFETY HANDLING PROCEDURES: None

FOR ADDITIONAL PROTOCOL INFORMATION SEE THE STANDARD OPERATING PROCEDURE FOR THE ABOVE TEST TYPE.*

VARIANTS FROM THE STANDARD OPERATING PROCEDURE FOR THIS TEST:
1 Control group. 1 Test group.
10 treatments 1 dose level
Blood analysis for lead at 0, 5, 10 and 15 days

O. Fayes Haskell
SIGNATURE OF STUDY DIRECTOR

10/25/79
DATE OF APPROVAL

*ADDITIONAL REFERENCE:
HASKELL LABORATORY REPORT NO. 206-75

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

SHORT-TERM STUDY PROTOCOL SHEET

MR NUMBER: 3540-001
HASKELL NUMBER: 13,257
NAME & SYNONYM: Paint, Dulux Enamel

TYPE TEST: Skin-Misc.
DOSAGE LEVELS: 1ml of 13,257+1.2 H-13,143 + 1ml of 13,257 + 60% A-13,163
PROPOSED STARTING DATE: 2/4/80
PROPOSED COMPLETION DATE: 18 Feb.
DISPOSAL OF WASTE MATERIALS: Waste jar

SPECIAL SAFETY HANDLING PROCEDURES: SOP

FOR ADDITIONAL PROTOCOL INFORMATION SEE THE STANDARD OPERATING PROCEDURE FOR THE ABOVE TEST TYPE.*

VARIANTS FROM THE STANDARD OPERATING PROCEDURE FOR THIS TEST:

IS THIS STUDY INTENDED FOR THE FDA? ☐ YES ☑ NO

D Lewis Dowell
SIGNATURE OF STUDY DIRECTOR

2/4/80
DATE OF APPROVAL

*ADDITIONAL REFERENCE:
HASKELL LABORATORY REPORT NO. 206-75

Revised 12/5/79

PROTOCOL FOR 15-DAY SKIN ABSORPTION STUDY WITH (H-13,257) PAINT, DULUX ENAMEL AND (H-13,163) LEAD NAPHTHANATE

Test Materials: H-13,257 - Paint, Dulux Enamel containing 0.415% of 24% Lead Naphthanate Solution

H-13,163 - 24% Lead Naphthanate Solution

Test Animals: 30 male New Zealand albino rabbits will be taken from stock after they have been quarantined for approximately 10-14 days. The rabbits will be weighed prior to the start of the test and every 5 days thereafter. The animals will be arranged in 3 groups of ten with the average weight of each group being approximately the same.

Group I - Control (water)

Group II - H-13,257 and H-13,163 (Paint, Dulux Enamel containing 1.2% Lead Naphthanate by weight)

Group III - H-13,257 and H-13,163 (Paint, Dulux Enamel containing 6% Lead Naphthanate by weight)

Treatment and Preparation of Stock Suspension:

A. The control group (I) will be administered 1.0 ml of distilled water on the shaved intact skin of their backs per treatment. Treatments will be administered once/day for 10 consecutive days. The test material will not be washed off of the animal at any time during the study. The treated area will be covered with a small (~1-1/2" x 1") plastic shield, then covered with Saran® Wrap and secured with adhesive wrapping.

B. For Group II, a stock suspension of H-13,257 containing 1.2% H-13,163 will be made in the following manner (on a weight % basis):

1. Weigh out 4.604 g of Lead Naphthanate (H-13,163).
2. Add to it 95.396 g of Paint, Dulux Enamel (H-13,257) containing 0.415 wt. % Lead Naphthanate.

This suspension will be applied to Group II test animals using the procedure in A and wrapped accordingly.

C. For Group III a stock suspension of H-13,257 containing 6% H-13,163 will be made in the following manner (on a weight % basis):

1. Weigh out 24.687 g of Lead Naphthanate (H-13,163).
2. Add to it 75.313 g of Paint, Dulux Enamel (H-13,257) containing 0.415 wt. % Lead Naphthanate.

This suspension will be applied to Group III test animals using the procedure in A and wrapped accordingly. All animals will remain wrapped for 6 hours after treatment.

Parameters:

Blood will be taken from a vein in the ear of all 3 groups of rabbits on day 0. Blood will be taken in the same manner from test groups II and III on days 5 and 10. On day 15, blood will again be taken from controls and the 2 test groups.

All blood analyses will be done by the Analytical Section of the Technical Services Division at Haskell Lab.

PA:scg
1/31/80

Prepared By: Polly Ashley
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Biochemist

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George E Bettinger
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Chief, Technical Services Section

N. Krivanek
Neil D. Krivanek
Consultant, Industrial Hygiene

ATTACHMENT

Technical Time = $57/hr.
Other = $26/hr.

BUDGET - $12,000.00

Expenses		
Analytical Expenses	$5,250.00	
Lab Assistants		
Shaving	260.00	
Holding	875.00	
Technical		
Bleeding	484.50	
Treating	570.00	
Report	200.00	
Pretest Work	~800.00	
Other (Technicians)		
Bleeding	442.00	
Pretest Work	156.00	
Cost of animals per die m	420.00	(14.00 ea. - 30) (1.05/day/animal)
Estimated Total Cost	$9,768.50	