

Industrial BIO-TEST Laboratories, Inc.  
1810 FRONTAGE ROAD  
NORTHBROOK, ILLINOIS 60062

(b) (4)

(b) (4)

REPORT TO

(b) (4)

HUMAN REPEATED INSULT PATCH TEST WITH  
FIVE EXPERIMENTAL SAMPLES

MAY 24, 1976

(b) (4)

(b) (4)

TINUVIN 770

(b) (4)

Fabric (b) (4) = Polypropylene knitted fiber  
treated with 0.25% TINUVIN  
770 (b) (4) and 0.1%  
IRGANOX 1010

Fabric (b) (4) = Polypropylene knitted fiber  
treated with 0.50% TINUVIN  
770 (b) (4) and 0.1%  
IRGANOX 1010

PERMANENT RECORD FILE

Industrial Medicine

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*Industrial BIO-TEST Laboratories, Inc.*

1810 FRONTAGE ROAD  
NORTHBROOK, ILLINOIS 60062

May 24, 1976

(b) (4)

Re: IBT No. (b) (4) - Human Repeated Insult Patch  
Test with Five Experimental Samples

We are submitting herewith our laboratory report prepared in  
connection with the above study.

Very truly yours,

*J. C. Calandra*

J. C. Calandra  
President

JCC:bp

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REPORT TO

(b) (4)

HUMAN REPEATED INSULT PATCH TEST WITH  
FIVE EXPERIMENTAL SAMPLES

MAY 24, 1976

(b) (4)

I. Introduction

Five experimental samples were received from (b) (4) for evaluation of their skin irritating and skin sensitizing properties employing 3 panels of 50 human test subjects each. The test materials were identified as follows:

Polypropylene (1.0% (b) (4))  
Polypropylene (0% (b) (4))  
Fabric (b) (4)  
Fabric (b) (4)  
Tinuvin 770 (b) (4)

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## II. Summary

A human repeated insult patch test utilizing 3 panels of 50 human subjects each was conducted with 5 experimental samples. The test materials were identified as follows:

1. Polypropylene (1.0% (b) (4))
2. Polypropylene (0% (b) (4))
3. Fabric (b) (4)
4. Fabric (b) (4)
5. Tinuvin 770 (b) (4)

The test materials 1 through 4 were evaluated as received. Tinuvin 770 (b) (4) was evaluated as a 0.5% dilution (w/v) in corn oil. A summary of the reaction scores during the induction applications is presented below.

Test Material	No. of Reactors	No. of Reactions/ No. of Patches Applied	No. of Reactions with Scores of:								
			0	1	2	3	4	5	6	7	8
Polypropylene (1.0% (b) (4))	1	2/450	448	1	1	0	0	0	0	0	0
Polypropylene (0% (b) (4))	1	2/450	448	2	0	0	0	0	0	0	0
Fabric (b) (4)	1	1/450	449	0	1	0	0	0	0	0	0
Fabric (b) (4)	0	0/450	450	0	0	0	0	0	0	0	0
Tinuvin 770 (b) (4) 0.5% in corn oil	1	2/450	448	1	1	0	0	0	0	0	0

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Based on the incidence and severity of the reactions, test materials Polypropylene (1.0% (b) (4)), Polypropylene (0% (b) (4)), Fabric (b) (4) and Tinuvin 770 (Batch32131, 0.5% in corn oil) would be considered extremely weak primary skin irritants under the exaggerated test conditions. Test material Fabric (b) (4) showed no irritating reactions (all scores 0) in any of the subjects tested.

There was no evidence of skin sensitization noted following the challenge application of all of the materials tested.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

(b) (4)

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### III. Procedure

Three panels of 50 human subjects each were employed in the investigation. The composition of the test populations is shown in Tables I through III.

The repeated insult technique was used in the patch test which called for a series of 9 induction patches of each test material to be placed on each of the subjects. The series was followed 12 days later by a single challenge patch of each test material to detect skin sensitization.

The series of 9 induction patches was applied according to the following schedule. A patch of each test material was applied on Monday, Wednesday and Thursday and allowed to contact the skin for 24 hours, after which time it was removed and the skin site graded for irritation. Thursday's patch was placed immediately after removal and grading of Wednesday's application. After the ninth induction patch had been placed, a nonpatching period of 12 days elapsed before the challenge patch was applied to detect sensitization reactions. For this 24-hour patch, a new skin site was used. This site was invariably chosen adjacent to the induction site; i.e., one where repeated applications had been made during the series of 9 induction patches. This patch was observed 24, 48 and 72 hours following application to detect immediate and delayed sensitization reactions.

Skin applications of each test material were made using Readi-Band\* clear plastic patches 1-1/2" x 1-1/2" square with nonwoven Webril centers.

\* Parke, Davis & Company, Detroit, Michigan

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TABLE I

TEST MATERIALS: Polypropylene (1.0% (b) (4)) and Polypropylene (0% (b) (4))

## Human Repeated Insult Patch Test

## Composition of Test Population

Sex	Age Range (years)	Race	No. of Subjects
Male	20-50	Caucasian	27
	32	Negro	<u>1</u>
		Subtotal -	28
Female	18-59	Caucasian	22
		Subtotal -	<u>22</u>
		Total -	50

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TABLE II

TEST MATERIALS: Fabrics (b) (4)

## Human Repeated Insult Patch Test

## Composition of Test Population

Sex	Age Range (years)	Race	No. of Subjects
Male	27-64	Caucasian	2
Female	24-61	Caucasian	<u>48</u>
		Total -	50

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TABLE III

TEST MATERIAL: Tinuvin 770 (b) (4) 0.5% in Corn Oil)

## Human Repeated Insult Patch Test

## Composition of Test Population

Sex	Age Range (years)	Race	No. of Subjects
Male	18-60	Caucasian	28
Female	21-66	Caucasian	<u>22</u>
		Total -	50

Test materials Polypropylene (1.0% (b) (4)), Polypropylene (0% (b) (4)), Fabric (b) (4) and Fabric (b) (4) were cut into 1/2" x 1/2" squares and placed on a patch premoistened with tap water just prior to application. Tinuvin 770 (Batch32131) was patched at a concentration of 0.5% in corn oil. Approximately 0.05 ml of the test material was placed on the Webril pad just prior to application.

The scoring criteria used for skin irritation reactions are shown in Table IV.

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TABLE IV

TEST MATERIALS: Polypropylene (1.0% (b) (4)),  
 Polypropylene (0% (b) (4)), Fabric (b) (4),  
 Fabric (b) (4) and Tinuvin 770 (b) (4)

## Human Repeated Insult Patch Test

## Scoring Criteria for Skin Irritation Reactions

Erythema and Eschar Formation

No reaction	0
Very slight erythema (barely perceptible)	1
Mild, well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total possible erythema score	4

Edema Formation

No reaction	0
Very slight edema (barely perceptible)	1
Slight edema (edge of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (area raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score	4
Total possible irritation score	8

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#### IV. Results

The results of the repeated insult patch test with Polypropylene (1.0% (b) (4)), Polypropylene (0% (b) (4)), Fabric (b) (4) and Tinuvin 770 (Batch<sup>3</sup> 2131, 0.5% in corn oil) are presented in Tables V through VIII. The tables cite scores for erythema and edema (plus their sums) for each application. Those subjects showing no reaction (all scores 0) are not tabulated.

These data are summarized in Tables IX through XII.

Test material Fabric (b) (4) produced no irritation through the induction phase (all scores 0).

There was no evidence of skin sensitization noted with any of the subjects to any of the materials tested.

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TABLE V

TEST MATERIAL: Polypropylene (1.0% (b) (4))

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		1			2			3			4			5		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
50	C-M-35	0	0	0	0	0	0	1	0	1	2	0	2	0	0	0

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TABLE V continued

TEST MATERIAL: Polypropylene (1.0% (b) (4))

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		6			7			8			9			Challenge		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
50	C-M-35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Er = Erythema  
Ed = Edema  
T = Total

C = Caucasian

M = Male

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TABLE VI

TEST MATERIAL: Polypropylene (0% TK (b) (4))

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		1			2			3			4			5		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
33	C-M-23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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TABLE VI continued

TEST MATERIAL: Polypropylene (0% (b) (4))

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:												Challenge		
		6			7			8			9			Er	Ed	T
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
33	C-M-23	0	0	0	0	0	0	1	0	1	1	0	1	0	0	0

Er = Erythema  
Ed = Edema  
T = Total

C = Caucasian

M = Male

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TABLE VII

TEST MATERIAL: Fabric (b) (4)

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		1			2			3			4			5		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
16	C-F-40	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0

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TABLE VII continued

TEST MATERIAL: Fabric (b) (4)

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		6			7			8			9			Challenge		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
16	C-F-40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Er = Erythema  
Ed = Edema  
T = Total

C = Caucasian

F = Female

000114

TABLE VIII

TEST MATERIAL: Tinuvin 770 (b) (4) 0.5% in  
Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application									Number
		1			2			3			
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er
44	C-F-52	0	0	0	0	0	0	2	0	2	1

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TABLE VIII continued

TEST MATERIAL: Tinuvin 770 (b) (4) 0.5% in Corn Oil)

Human Repeated Insult Patch Test

Individual Irritation Scores

Subject Number	Race Sex Age	Scores after Application Number:														
		6			7			8			9			Challenge		
		Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
44	C-F-52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Er = Erythema  
Ed = Edema  
T = Total

C = Caucasian

F = Female

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TABLE IX

TEST MATERIAL: Polypropylene (1.0% (b) (4))

Human Repeated Insult Patch Test

Summary of Reactions

		Scores after Application Number:									Grand	
		1	2	3	4	5	6	7	8	9	Challenge	Totals*
Reactions with												
scores of:	1	0	0	1	0	0	0	0	0	0	0	1
	2	0	0	0	1	0	0	0	0	0	0	1
	3	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0	0	0	0
	8	0	0	0	0	0	0	0	0	0	0	0
Total reactions		0	0	1	1	0	0	0	0	0	0	2
Total nonreactions		50	50	49	49	50	50	50	50	50	50	448
Total patches applied		50	50	50	50	50	50	50	50	50	50	450
Incidence of												
reactions:	Fraction	0/50	0/50	1/50	1/50	0/50	0/50	0/50	0/50	0/50	0/50	2/450
	Percent	0.0	0.0	2.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4

\* Challenge application not included in the Grand Totals.

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TABLE X

TEST MATERIAL: Polypropylene (0% (b) (4))

## Human Repeated Insult Patch Test

## Summary of Reactions

		Scores after Application Number:										Grand
		1	2	3	4	5	6	7	8	9	Challenge	Totals*
Reactions with												
scores of:	1	0	0	0	0	0	0	0	1	1	0	2
	2	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0	0	0	0
	8	0	0	0	0	0	0	0	0	0	0	0
Total reactions		0	0	0	0	0	0	0	1	1	0	2
Total nonreactions		50	50	50	50	50	50	50	49	49	50	448
Total patches applied		50	50	50	50	50	50	50	50	50	50	450
Incidence of												
reactions:	Fraction	0/50	0/50	0/50	0/50	0/50	0/50	0/50	1/50	1/50	0/50	2/450
	Percent	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.4

\* Challenge application not included in the Grand Totals.

000118

TABLE XI

TEST MATERIAL: Fabric (b) (4)

Human Repeated Insult Patch Test

## Summary of Reactions

		Scores after Application Number:									Grand	
		1	2	3	4	5	6	7	8	9	Challenge	Totals*
Reactions with												
scores of:	1	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	1	0	0	0	0	0	0	0	1
	3	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0	0	0	0
	8	0	0	0	0	0	0	0	0	0	0	0
Total reactions		0	0	1	0	0	0	0	0	0	0	1
Total nonreactions		50	50	49	50	50	50	50	50	50	50	449
Total patches applied		50	50	50	50	50	50	50	50	50	50	450
Incidence of												
reactions:	Fraction	0/50	0/50	1/50	0/50	0/50	0/50	0/50	0/50	0/50	0/50	1/450
	Percent	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2

\* Challenge application not included in the Grand Totals.

000119

TABLE XII

TEST MATERIAL: Tinuvin 770 (b) (4) 0.5 % in Corn Oil)

## Human Repeated Insult Patch Test

## Summary of Reactions

		Scores after Application Number:										Grand
		1	2	3	4	5	6	7	8	9	Challenge	Totals*
Reactions with												
scores of:	1	0	0	0	1	0	0	0	0	0	0	1
	2	0	0	1	0	0	0	0	0	0	0	1
	3	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0	0	0	0
	8	0	0	0	0	0	0	0	0	0	0	0
Total reactions		0	0	1	1	0	0	0	0	0	0	2
Total nonreactions		50	50	49	49	50	50	50	50	50	50	448
Total patches applied		50	50	50	50	50	50	50	50	50	50	450
Incidence of												
reactions:	Fraction	0/50	0/50	1/50	1/50	0/50	0/50	0/50	0/50	0/50	0/50	2/450
	Percent	0.0	0.0	2.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4

\* Challenge application not included in the Grand Totals.

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