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



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REPORT TO

DOW CHEMICAL U.S.A.

HUMAN REPEATED INSULT PATCH TEST WITH
DBDO-1 AND XD8186.02

P.O. NO. 917780

JUNE 4, 1975

IBT NO. 636-06545

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Industrial BIO-TEST Laboratories, Inc.

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

June 4, 1975

Dr. K. J. Olson
Health & Environmental Research
Toxicology Research Laboratory
Dow Chemical U. S. A.
Building 1803
Midland, Michigan 48640

Dear Dr. Olson:

Re: IBT No. 636-06545 - Human Repeated Insult Patch
Tests with DBDO-1 and XD8186.02 - P. O. No. 917780
and with DPM-1 and DPM-2 - P. O. No. 917778

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

Very truly yours,

J. C. Calandra

J. C. Calandra
President

JCC:bp

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I. Introduction

Two samples identified as DBDO-1 and XD8186.02 were received from Dow Chemical U.S.A. for evaluation of their skin irritating and skin sensitizing properties employing 200 human subjects. Test material DBDO-1 was evaluated as received. Test material XD8186.02 was prepared weekly as a 2.0% w/v aqueous solution using Sterile Water for Injection, U.S.P. and was kept refrigerated.

II. Summary

A human repeated insult patch test employing 200 subjects was conducted with 2 test materials identified as DBDO-1 and XD8186.02. Test material DBDO-1 was evaluated as received, while XD8186.02 was prepared as a 2.0% (w/v) aqueous solution in sterile water.

The results of the series of induction patches are 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
DBDO-1	5	5	1800	1795	3	1	1	0	0	0	0	0
XD8186.02	10	11	1800	1789	11	0	0	0	0	0	0	0

Based on the incidence and severity of the reactions, neither test material would be considered as a primary skin irritant under the exaggerated test conditions.

There was no evidence of skin sensitization observed with either test material in any of the subjects.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

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III. Procedure

Two hundred human subjects were employed in the investigation. The composition of the test population is shown in Table I.

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 upper arm (outer surface) of the male subjects was utilized for patching, while the female subjects were patched on the upper back, shoulder area.

The series of 9 induction patches for each test material was applied according to the following schedule. A patch 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 of each test material 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 patches. This site was observed at patch removal for sensitization reactions and again after 24 and 48 hours to detect possible delayed reactions.

The skin applications were made using Readi-Band* "hypoallergenic nonirritating" clear plastic patches 1-1/2" x 1-1/2" square with nonwoven Webril centers. Approximately 0.05 ml of each test material was placed on the Webril center of the patch just prior to application.

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

* Parke, Davis & Company, Detroit, Michigan

TABLE I

TEST MATERIALS: DBDO-1 and XD8186.02

Human Repeated Insult Patch Test

Composition of Test Population

Sex	Age Range (years)	Race	No. of Subjects
Male	19-63	Caucasian	64
	31-42	Negro	11
	25-35	Oriental	<u>5</u>
		Subtotal -	80
Female	21-58	Caucasian	119
	32	Negro	<u>1</u>
		Subtotal -	<u>120</u>
		Total	200

TABLE II

TEST MATERIALS: DBDO-1 and XD8186.02

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

IV. Results

The results of the repeated insult patch test are presented in Tables III and IV. 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 V and VI.

There was no evidence of skin sensitization noted with either of the test materials in any of the subjects tested.

TABLE III
TEST MATERIAL: DBDO-1

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
17	C-M-27			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
84	C-F-31			2	0	2	0	0	0	0	0	0	0	0	0	0	0	0
177	C-F-32			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
180	C-F-35			0	0	0	1	0	1	0	0	0	0	0	0	0	0	1
185	C-F-52			0	0	0	1	0	1	0	0	0	0	0	0	0	0	0

TABLE III continued
 TEST MATERIAL: DBDO-1
 Human Repeated Insult Patch Test
 Individual Irritation Scores

Subject Number	Race	Sex	Age	6		7		8		9		Challenge			
				Er	Ed	T	Er	Ed	T	Er	Ed	T	Er	Ed	T
17	C-M-27			2	1	3	0	0	0	0	0	0	0	0	0
84	C-F-31			0	0	0	0	0	0	0	0	0	0	0	0
177	C-F-32			0	0	0	0	0	0	0	0	0	0	0	0
180	C-F-35			0	0	0	0	0	0	0	0	0	0	0	0
185	C-F-52			0	0	0	0	0	0	0	0	0	0	0	0

Er = Erythema
 Ed = Edema
 T = Total
 C = Caucasian
 M = Male
 F = Female

0 0 1 4

TABLE IV continued

TEST MATERIAL: XD8186.02

Human Repeated Insult Patch Test

In Divided Irritation Scores

Subject Number	Race	Sex	Age	6			7			8			9			Challenge	
				Er	Ed	T	Er	Ed									
84	C-F	31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
86	C-F	34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
88	C-F	27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
92	C-F	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
157	C-F	52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
164	C-F	32	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
166	C-F	32	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
180	C-F	35	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
185	C-F	52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
193	C-M	34	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
F = Female

TABLE V
 TEST MATERIAL: DBDO-1
 Human Repeated Insult Patch Test
 Summary of Reactions

Reactions with scores of:	Scores after Application Number:								Grand Totals*				
	1	2	3	4	5	6	7	8		9	Challenge		
0	0	2	0	0	1	0	0	0	0	0	0	0	3
1	1	0	0	0	0	0	0	0	0	0	0	0	1
2	0	0	0	0	0	1	0	0	0	0	0	0	1
3	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0
Total reactions	1	2	0	0	1	0	0	0	0	0	0	0	0
Total nonreactions	199	198	200	200	199	199	200	200	200	200	200	200	5
Total patches applied	200	200	200	200	200	200	200	200	200	200	200	200	1795
Incidence of reactions:	1/200	2/200	0/200	0/200	1/200	1/200	0/200	0/200	0/200	0/200	0/200	0/200	5/1800
Percent	0.5	1.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0	0.3	

* Challenge application not included in the Grand Totals.

TABLE VI
 TEST MATERIAL: XD8186.02
 Human Repeated Insult Patch Test

Summary of Reactions

Reactions with scores of:	Scores after Application Number:								Grand Totals*		
	1	2	3	4	5	6	7	8		9	Challenge
1	0	1	2	2	1	3	0	1	1	0	11
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	1	2	2	1	3	0	1	1	0	0
Total nonreactions	200	199	198	198	199	197	200	199	199	200	11
Total patches applied	200	200	200	200	200	200	200	200	200	200	1789
Incidence of reactions:	0/200	1/200	2/200	2/200	1/200	3/200	0/200	1/200	1/200	0/200	11/1800
	0.0	0.5	1.0	1.0	0.5	1.5	0.0	0.5	0.5	0.0	0.6

* Challenge application not included in the Grand Totals.



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