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UNIVERSITY OF CINCINNATI
Department of Preventive Medicine and Industrial Health

The Kettering Laboratory
College of Medicine - Eden Ave.
Cincinnati 19, Ohio

January 25, 1952

Mr. Manfred Bowditch
Lead Industries Association
420 Lexington Avenue
New York 17, New York

Dear Mr. Bowditch:

I am enclosing the final report on the six lead compounds which were evaluated by repetitive human patch tests. If there are any questions about the details of the report, please do not hesitate to communicate with me about them.

You understand, I am sure, why it is unwise to predict usage reactions from our results insofar as films containing these compounds are concerned. A vinyl plastic containing any of the stabilizers would probably provide much less cutaneous contact with the stabilizer itself than the patch device used in the experiment. In our initial discussions you will recall, however, that it was decided to evaluate the compounds out of their resin milieu before going on to tests which would employ films incorporating the stabilizers. As it turns out, the latter evaluation becomes quite necessary in order to understand what cutaneous reactions are possible from resins containing the lead compounds.

With kindest personal regards, I am

Very sincerely yours,

/s/ Raymond R. Suskind

Raymond R. Suskind, M.D.
Staff Dermatologist

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Encls.

THE CUTANEOUS IRRITANT AND SENSITIZING PROPERTIES OF A SERIES OF LEAD COMPOUNDS EMPLOYED AS STABILIZERS FOR VINYL RESINS

1. Purpose

The object of the experimental procedure was to determine the irritant and sensitising properties for human skin of six lead compounds submitted by the Lead Industries Association.

2. Conclusions

Under the conditions of the evaluation procedure used, five of the compounds were observed to evoke a small number of primary irritation reactions. They were dibasic lead stearate, tribasic maleate, normal lead salicylate, basic silicate white lead and basic carbonate white lead. The lead orthosilicate and silica gel was observed to evoke a moderate number of primary irritation reactions, but the results were not entirely consistent, in that two successive series of tests of this preparation on the same subjects, after an interval of 2 weeks, yielded different numbers of reactions. Sensitization did not appear to be a factor in the cutaneous reactions which were induced.

3. Materials

Materials: Each of six lead compounds was incorporated in a methocel vehicle which was made up by mixing 50 grams of methocel (4000 cps) with 750 grams of water. The compounds were used in the following concentrations:

Substance

#1. dibasic lead stearate (DS207 Dutch Boy) 1.0%

#2. tribasic lead maleate (Tribal Dutch Boy) 1.0%

#3. lead orthosilicate and silica gel (Plumb-O-Sil Dutch Boy) 6.0%

#4. normal lead salicylate (Normasal, Dutch Boy) 0.5%

#5. basic silicate white lead (Eagle Picher) 5.0%

#6. basic carbonate white lead (John R. MacGregor) 6.0%

The concentrations employed in this experiment represented the maximum concentration of each compound recommended for use in the commercial formulation of vinyl plastics.

4. Experimental Procedure

A small amount of each mixture was applied with a tongue blade upon the skin of the inner aspect of the upper arm of human subjects, covered and retained in place with a Commercial patch (Band-Aid Patch) which consisted of a 2 x 2 cm gauze square and a ventilated adhesive cover 3.5 x 3.5 cm. The application sites were observed 48 hours and 96 hours after application. The procedure was repeated two weeks after the initial application employing the same cutaneous areas of the identical group of subjects.

5. Subjects

Two hundred and forty-six subjects were employed in the initial test of which 194 were available for retesting. The subjects were all females with presumably normal skin.

6. Results

The results are presented in tabular form on the following pages

Patch Test Observations - First Series

Substance	Number of Subjects	Negative Reactions	Positive Reactions			Total Number Positive Reactions	Per Cent Positive Reactions
			1+	2+	3+		
1	246	240	5	1	0	6	2.4
2	246	241	2	3	0	5	2.0
3	246	221	19	6	0	25	10.2
4	246	236	6	4	0	10	4.1
5	246	237	8	1	0	9	3.7
6	246	241	3	2	0	5	2.0

Patch Test Observations - Second Series

Substance	Number of Subjects	Negative Reactions	Positive Reactions			Total Number Positive Reactions	Per Cent Positive Reactions
			1+	2+	3+		
1	194	185	9	1	0	10	5.2
2	194	190	4	0	0	4	2.1
3	194	188	5	1	0	6	3.1
4	194	188	5	1	0	6	3.1
5	194	188	3	3	0	6	3.1
6	194	190	4	0	0	4	2.1

None of the subjects in whom reactions were observed in the first series reacted in the second series.

7. Discussion

In response to the first series of applications the percentage of subjects exhibiting reactions to one or another of the six compounds ranged from 2.0 to 10.2, the greatest number being evoked by contact with the orthosilicate and silica gel. Following the second series of applications the incidence of reactions ranged from 2.1 to 5.2 per cent. The frequency with which reactions were evoked by four of the substances, i.e., tribasic lead maleate, normal lead salicylate, basic silicate white lead and basic carbonate white lead did not differ significantly in the first and second tests. On the other hand only 3.1 per cent of the subjects reacted to the orthosilicate and silica gel in the second series, whereas 10.2 per cent reacted in the first. None of the subjects whose skin reacted after the first application, reacted following reapplication two weeks later. In the case of the dibasic stearate the percentage of reactors was slightly greater in the second series. The difference in the percentage of reactions in the two series can only be explained by differences in local physical factors in the two series of tests. These factors are not easily controlled and include ambient temperature, humidity, sweating, exercise, local friction and pressure (by outer clothing), type of cutaneous contact, and local ventilation. Nevertheless, the number of reactions was such that it may be said that under the conditions

of the present test the dibasic lead stearate, tribasic lead maleate, normal lead salicylate, basic silicate white lead and basic carbonate white lead may be mildly irritating and that the orthosilicate and silica gel may be moderately irritating. Since this patch test evaluation does not duplicate the usage conditions, it would be unwise to conclude that any of the six lead compounds would be mildly or moderately irritating when incoporated in the plastic.

8. Recommendations

It is suggested that similar patch tests be carried out on 200 subjects employing vinyl plastics containing maximum concentrations of each of the six lead compounds, with suitable vinyl plastic control films which do not contain the lead compounds.

From the Kettering Laboratory in the Department of Preventive Medicine and Industrial Health and the Department of Dermatology and Syphilology, College of Medicine, University of Cincinnati.

Observations by:

Raymond R. Suskind, M.D.

Junee Jambor, M.D.

Ruth Forney, R.N.

Report by:

Raymond R. Suskind, M.D.

Approved: /s/ Robert A. Kehoe
Robert A. Kehoe, M.D.

January 24, 1952