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A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands

by

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TABLE OF CONTENTS

LIST OF TABLES

1. INTRODUCTION

1.1 Purpose and Scope

This report was prepared for the U.S. Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT), to supply specific information needed to perform exposure assessments. The purpose of this report is to present data collected in three laboratory trials designed to quantify the amount of liquid deposited onto the surface of hands. This information is needed to calculate dermal exposure using the film thickness methodology developed in Volume 7 of the Methods for Assessing Consumer Exposure to Chemical Substances series (Jennings et al. 1987).[1] For information regarding other dermal exposure methods and for specific information on the development of the film thickness method for determining dermal exposure, the reader is referred to Volume 7.

The basic equation for estimating annual dermal exposure via a liquid film is as follows:

$$PDR = WF \times DSY \times DIL \times T \times AV \times FQ \quad (1)$$

where

PDR = potential dose rate (mg/yr)
WF = weight fraction of chemical substance in product
DSY = density of formulation (mg/cm^3)
DIL = dilution fraction
AV = skin surface area exposed (cm^2/event)
FQ = frequency of events per year

and

[1]Jennings PD, Hammerstrom KA, Adkins LC, Chambers T, Dixon DA. 1987. Methods for Asssing Exposure to Chemical Substances. Volume 7. Methods for Assessing Consumer Exposure to Chemical Substances. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. EPA 560/5-85-007.

T = film thickness of liquid on skin surface (cm)

$$= \frac{\text{amount of liquid retained on skin (mg/cm}^2\text{)}}{\text{density of liquid (g/cm}^3\text{) x 1,000 (mg/g)}} \quad (2)$$

The first three variables in Equation (1) are used to estimate the concentration of the chemical being assessed. The volume of liquid is determined by multiplying the film thickness (T) of the liquid on the surface of the skin (cm) by the area of skin (AV) likely to be exposed per event (cm^2/event). Because of the paucity of data on film thicknesses on the surface of hands (T), laboratory studies were conducted to generate the needed data. The complexity and expense of designing an experiment that controls all variables and examines a random population was beyond the scope of this set of laboratory experiments. Instead, the studies were designed to generate rough, order-of-magnitude values for film thicknesses to be used as a first cut method to estimate dermal exposure assessments. The data used to calculate the film thickness using Equation (2) are presented in the following chapters.

Three sets of experiments were performed applying various liquids to the hands of volunteer human subjects. The amount of liquid retained on the subjects' hands and the density of the liquid were measured to determine the liquid film thickness. The amount of liquid retained was measured as a function of the identity of the experimental subject, the type of liquid applied, and the method of experimental application and a subsequent removal. Replicate liquid retention measurements were taken for each subject-liquid-application/ removal combination.

Six liquids were selected for use in the original study: three non-aqueous and three water-based liquids. The liquids were selected because they were nontoxic to the human subjects and because they represented a range of viscosities and, therefore, a range of likely retention values as well. Retention measurements for the water-based liquids of the first experiment were non-uniform and difficult to reproduce. These difficulties may have been caused by an inability to estimate the possibly high volatilization/evaporation losses of the liquids. A further difficulty with the measurements was associated with somewhat different experimental procedures employed in the first and later experiments. The differences between first and later (second and third) experiments included use of a different type of one liquid, use of a different type of liquid wipe cloth, and use of slightly different methods of liquid application and removal by different

experimental personnel. Because of these differences and the difficulties they posed for the analysis of data from the first experiment, the data on water-based liquids were dropped from further consideration and are not presented in this report.

The current study focuses on retention on hands of nonaqueous liquids. For each subject-liquid combination, three different methods of liquid application, or testing, were employed: initial wipe, secondary wipe, and immersion. The initial wipe test consisted of the subjects wiping their hands with a cloth saturated in the liquid. The amount of liquid retained on the hands was measured immediately after the application and also after subsequent partial and full removals by a dry cloth designed to remove liquid from the hands. The dry cloth was weighed before and after each test to obtain the amount of liquid removed. Subjects' hands were thoroughly washed before each initial wipe application.

Secondary wipe applications were the same as initial wipe applications except for the important difference that secondary wipe tests were conducted directly after initial wipe tests with no intervening washing of hands. The secondary wipe tests were thus designed to measure decreased retentions caused by the skin's being saturated with liquid from the initial wipes. Immersion applications, designed to simulate worst-case maximum exposure events, consisted of dipping subjects' hands into a container of the liquid. The amount of liquid retained on the hands was measured indirectly immediately after immersion by weighing the jar of liquid before and after immersion. The amount of liquid was also measured after a partial removal by a dry cloth by weighing the cloth before and after it contacted the subject's hands. As with the initial wipe tests, the subjects' hands were thoroughly washed before each immersion test replicate.

1.2 Organization of the Report

Section 2 of this report describes the experimental procedures used during the study. Details of all three studies are included. Section 3 reports on data analysis and interpretation of the data. Section 4 summarizes the main experimental results and presents them, tabularly, as mean values.

Appendix A contains the documentation on compliance with 45 CFR 46 - The Protection of Human Subjects. Appendix B describes the method used to calculate the surface area of the subjects' hands. Appendix C describes the methods used to determine the density and viscosity of the test liquids. The laboratory reports are also included. Appendix D details the liquid application and removal procedures, which are written as detailed instructions for the investigator. Appendix E presents the raw data for all three sets of experiments using the oil-based liquids. As mentioned in Section 1.1, the data for the water-based liquids collected in the first two lab studies have been dropped because the data were found to be unreliable; therefore, those data are not presented in this volume. Appendix F presents the statistical analysis tables for the raw data.

2. EXPERIMENTAL METHOD

Measurements of the amount of liquid retained on the hands of four human subjects were made. The measurements were taken for each of three different liquids that were separately applied to the subjects' hands. For each subject and each liquid, the measurements were repeated for each of three different liquid application techniques (initial wipe, secondary wipe, and immersion) and two different removal techniques (partial removal, full removal). The first two application techniques (initial wipe and secondary wipe) were used with both removal techniques (partial and full), and the remaining application technique (immersion) was used with only one removal technique (partial removal). Four liquid retention replicates (one from Experiment Two and three from Experiment Three) were taken for each of the single application/double removal test combinations (i.e., initial wipe application/partial and full removal and secondary wipe application/partial and full removal) giving

4 replicates per subject-liquid-application/removal combination
x 4 subjects
x 3 liquids
x 2 application/removal techniques
= 96 replicates

for each combination or 192 total liquid retention replicates for both application/removal techniques. Six replicates (three each from Experiments Two and Three) were taken for the single application/single removal combination (immersion test) giving

6 replicates per subject-liquid-application/removal combination
x 4 subjects
x 3 liquids
x 1 application/removal technique
= 72 replicates

for that test combination.

Thus, a three-factor experimental design was used to collect and analyze the liquid retention data. The three factors, or explanatory variables, influencing the amount of liquid retained on skin were (1) the identity of the human subjects (and the surface areas of their hands) on which the liquids were applied, (2) the different types of liquid applied (with different viscosities and densities), and (3) the different methods used to apply and remove the various

liquids from the subjects' hands. The remainder of this section discusses the measurement procedures associated with each of the three experimental factors.

2.1 Experimental Subjects

Amounts of liquid (mg) were applied to and removed from the hands of the four human subjects (A, B, C, D). Dividing the amounts of liquid retained by the surface areas (cm^2) of the subjects' hands gave the amount of liquid retained per unit surface area of skin (mg/cm^2). Since human subjects were involved in the experiments, their protection fell under regulation of 45 CFR 46 of the Department of Health and Human Services (HHS). The project was conducted according to the procedures of the regulation and was found to be in compliance by an institutional review board. Detailed compliance documentation for the first experiment is included in Appendix A. Since Experiments Two and Three used the same procedures and materials as Experiment One, these later experiments were also in compliance.

The total surface areas of the subjects' hands were estimated from the "cookie-cutter" formula:

$$SA = 2 \cdot S + p \cdot t$$

where

SA	=	Surface area of hand (cm^2)
S	=	Surface area of palm of hand or surface of back of hand (cm^2)
p	=	Perimeter of hand (cm)
t	=	Average thickness of hand (cm).

Individual hand tracings were used to estimate, by digitizer, S and p, and caliper measurements were used to estimate t. A detailed description of the measurement procedure used to determine SA is included in Appendix B of this report. The results of the procedure, the listings of p, t, S, and SA, for all four experimental subjects are listed in Table 2-1.

Table 2-1. Hand Measurements[a] of Experimental Subjects

Subject	t (cm)		p (cm)		S (cm^2)		SA (cm^2)		
	Left hand	Right hand	Left hand	Right hand	Left hand	Right hand	Left hand	Right hand	Both hands
A	2.8	2.7	106	106	170	164	637	614	1,250
B	2.1	2.1	90	88	115	103	419	391	810
C	2.5	2.5	98	99	148	150	541	548	1,090
D	2.5	2.8	107	107	168	163	603	626	1,230

[a] Measurements rounded to no more than three significant digits to reflect measurement error.

Source: Appendix B, Tables B-1 and B-2.

2.2 Liquids Applied

Initially, six liquids were selected for use in the study, but, as already noted, three were omitted because an acceptable experimental procedure to address volatilization/evaporation losses could not be developed for them. The liquids omitted were water/oil emulsion (50:50, water:water-soluble oil); water; and water/ethanol (50:50). The three liquids (all oils) that were used in the two experiments were:

- Mineral oil (Giant Food Inc.);
- Cooking oil (Crisco); and
- Bath oil (Gray Drugs, Inc. and Rite Aid, Inc.).

The oils were selected because of their suitability for human use (non-toxic) and their varying viscosities. The difference in viscosities, and slight difference in densities, was intended to lend some variability to the experimental results, thereby making the results more representative of actual exposure conditions. In all cases, the liquids were applied and removed with 100 percent cotton cloths.

The density and viscosity of each oil was measured by an outside laboratory. The results of the measurements are presented in Table 2-2. The measurements verified that the density and viscosity of each oil type were approximately the same for both experiments. A detailed description of the density and viscosity measurements is included in Appendix C.

2.3 Liquid Application and Removal Techniques

Three combined application/removal techniques, or tests, were used to expose subjects to the liquids selected for study. The methods used by the subjects to apply and remove each liquid from the subjects' hands are summarized here and described in detail in Appendix D of this report. In the initial wipe test, each subject's hands were first thoroughly washed and then the liquids were applied to their hands from a cloth saturated in the liquid. The amount of liquid first retained on the hands was then found by simply calculating the difference between the before and after application weights of the cloth (and holding cup). Separate dry removal cloths

Table 2-2. Viscosity[a] and Density[b] of Experimental Liquids

Liquid	Kinematic viscosity (cSt)[c]	Density (g/cm^3)
Mineral oil	160.2	0.870
Cooking oil	59.2	0.920
Bath oil	33.3	0.861

[a] Measured at 23°C for viscosity.

[b] Measured at 24.5°C for density.

[c] Centistokes, one one-hundreth stoke, the kinematic unit of viscosity; it is equal to the viscosity in poises divided by the density of the fluid in grams per cubic centimeter, both measured at the same temperature. (Hawley I, Goodrich G. 1981. The Condensed Chemical Dictionary. 10th ed. New York, NY: VanNostrand Reinhold Company.)

Source: Measured at Gascoyne Laboratories, see Appendix C.

were then used to wipe the hands both partially and fully (see Table 2-2 Appendix D for explanation of partial and full wipe procedures). Subtracting the differenced weighings of the removal cloth (and holding cup) from the amount of liquid first retained yielded the amount of liquid remaining on the hands after the partial and full removal, respectively. The experimental data are summarized in Appendix E, Table E-1.

A "secondary wipe" test was also performed on the subjects. The procedures of this test were the same as those of the initial wipe test with the important exception that the secondary wipe tests immediately followed the initial wipe tests with no intervening washing of hands. A detailed description of the secondary wipe experimental procedure is included in Appendix D, and the accompanying experimental data are listed in Appendix E, Table E-1.

The third application/removal test used in the project was an "immersion" test. In this test, subjects dipped their hands (thoroughly washed) directly into a container holding the liquid and then wiped their exposed hands, first partially then fully, with separate, initially dry, removal cloths. Because an analytical balance of sufficient combined capacity and accuracy did not exist to directly weigh the container of liquid before and after application, the amount of liquid first retained was indirectly estimated by adding the differenced weighings of both partial and full removal cloths (with holding cups) to the previously estimated amount remaining after "full" removal from the initial wipe test. The amount remaining after partial removal was estimated by subtracting the differenced weighing of the partial removal cloth from the amount estimated to be first retained. A detailed description of the immersion experimental procedure is included in Appendix D, and the accompanying experimental data are listed in Appendix E, Table E-2.

The amount of liquid retained (per unit area) on skin for each application/removal test combination divided by the previously measured densities of liquids gave the estimated film thickness of liquid on skin surface, T, needed for estimating dermal exposures from Equation (1).

3. DATA ANALYSIS AND INTERPRETATION

The liquid retention data for the three tests of this project (initial wipe, secondary wipe, immersion) were analyzed as data from a three-factor, fixed-effects analysis of variance (ANOVA) experimental design. The objective of the analysis was to determine which factors (human subject, liquid type, application/removal method) or combinations of factors had a significant effect on the variability of the experimental results for liquid retention per unit skin surface area (mg/cm^2). The ANOVA tables for the three tests are listed in Appendix F, Tables F-1 through F-5. The tables present the mean squares, variance ratios, and significance probabilities for the important factors of each test. In this section, the results of the analysis in terms of the tables of (liquid retention) means for each test are discussed.

3.1 Wipe Tests

Tables 3-1 and 3-2 present the following information for the initial and secondary wipe tests:

- Replicate means for each experimental subject (A, B, C, D)-liquid type (mineral oil, cooking oil, bath oil)- application/removal (application, partial removal, full removal) factor combination;
- Experimental subject (row) means for each application/removal level (application, partial removal, full removal); and
- Liquid type (column) means for each application/removal level.

The standard error for comparing the difference of any two row means, within or between the tables, is $\sqrt{(2 \times .053/12)} = 0.094$. If two row means differ by more than twice this amount, they are considered distinct at an approximate significance probability of 95 percent. Inspection of Tables 3-1 and 3-2 shows that, at each application/removal level, at least one, and usually more than one, pair of significantly different row means exists. Thus, as confirmed by the ANOVA of Appendix F, Tables F-1 through F-3, experimental subjects (rows) were a significant source of experimental variability: different subjects had significantly different capacities to retain liquid on the surface of their hands.

Table 3-1. Means of Liquid Amounts Retained on the Surface of Hands (mg/cm^2), Initial Wipe Test

	Application/removal[a] replicate means			Application/ removal[a] Row means[b,f]	Overall Row means[c,f]
	Mineral oil	Cooking oil	Bath oil		
Experimental subjects,					
A	1.61, 0.76, 0.59	3.05, 1.15, 0.63	1.93, 0.72, 0.22	2.20, 0.88, 0.48	1.19
B	1.28, 0.57, 0.24	1.79, 0.69, 0.20	1.59, 0.66, 0.29	1.55, 0.64, 0.24	0.81
C	1.20, 0.39, 0.11	2.17, 0.68, 0.36	1.23, 0.37, 0.13	1.53, 0.48, 0.20	0.74
D	1.33, 0.45, 0.02	1.27, 0.46, 0.08	1.22, 0.29, 0.04	1.27, 0.40, 0.05	0.57
Application/removal[a] column means[d,f]	1.36, 0.54, 0.24	2.07, 0.75, 0.32	1.49, 0.51, 0.17	1.64, 0.60, 0.24	
Overall column means[e,f]	0.71	1.05	0.72		0.83

[a] Table triplet entries = amount retained after application, amount retained after "partial" removal, amount retained after "full" removal.

[b] Standard error of each application/removal row mean = $\sqrt{(MSE/12)}$ = 0.067, where MSE = $^1/_3$(0.106 + 0.025 + 0.029) = 0.053 is the average error mean square from the ANOVA Tables F-1, F-2, and F-3 of Appendix F.

[c] Standard error of each overall row mean = $\sqrt{(MSE/36)}$ = 0.038.

[d] Standard error of each application/removal column mean = $\sqrt{(MSE/16)}$ = 0.058.

[e] Standard error of each overall column mean = $\sqrt{(MSE/48)}$ = 0.033.

[f] Standard error of each mean difference = $\sqrt{(2 \times \text{Standard error of each mean})}$.

Table 3-2. Means of Liquid Amounts Retained on the Surface of Hands (mg/cm^2), Secondary Wipe Test

	Application/removal[a] replicate means			Application/ removal[a] Row means[b,f]	Overall Row means[c,f]
	Mineral oil	Cooking oil	Bath oil		
Experimental subjects					
A	1.34, 0.46, 0.03	2.45, 0.65, 0.07	1.56, 0.44, 0.01	1.78, 0.52, 0.04	0.78
B	1.20, 0.52, 0.15	1.48, 0.55, 0.08	1.53, 0.56, 0.23	1.40, 0.54, 0.15	0.70
C	1.11, 0.27, 0.01	1.77, 0.41, 0.18	1.12, 0.30, 0.04	1.33, 0.33, 0.08	0.58
D	1.23, 0.40, 0.01	1.16, 0.31, -0.09	1.14, 0.34, 0.00	1.18, 0.35, -0.03	0.50
Application/removal[a] column means[d,f]	1.22, 0.41, 0.05	1.72, 0.48, 0.06	1.34, 0.41, 0.07	1.43, 0.43, 0.06	
Overall column means[e,f]	0.56	0.75	0.61		0.64

[a] Table triplet entries = amount retained after application, amount retained after "partial" removal, amount retained after "full" removal.

[b] Standard error of each application/removal row mean = $\sqrt{(MSE/12)}$ = 0.067, where MSE = $^1/_3(0.106 + 0.025 + 0.029)$ = 0.053 is the average error mean square from the ANOVA Tables F-1, F-2, and F-3 of Appendix F.

[c] Standard error of each overall row mean = $\sqrt{(MSE/36)}$ = 0.038.

[d] Standard error of each application/removal column mean = $\sqrt{(MSE/16)}$ = 0.058.

[e] Standard error of each overall column mean = $\sqrt{(MSE/48)}$ = 0.033.

[f] Standard error of each mean difference = $\sqrt{(2 \times \text{Standard error of each mean})}$.

Concerning the different liquids used in the tests, the standard error for the difference of any two column means is $\sqrt{(2 \times .053/16)} = 0.082$. Twice this amount is less than the difference of at least one and usually more than one pair of column means, at least for the application and partial removal levels of both initial and secondary wipe tests. Thus, as again confirmed by the ANOVA of Appendix F, liquid type was also a significant source of variability: liquids of different viscosities were retained in different amounts on the surface of hands. However, no correlation was observed between the viscosity and the amount retained.

It is also evident from both the column and row means in Tables 3-1 and 3-2 that the application/removal method was a significant source of variability. In other words, as confirmed by the ANOVA of Appendix F, significantly different amounts of liquid were retained after first application, partial removal, and full removal. For both tests, partial removal retentions were significantly less than first application retentions, and full removal retentions were significantly less than partial removal retentions. Thus, all three experimental factors--subject, liquid type, and application/removal method--had a significant impact on the amount of liquid retained on the surface of skin.

In addition to the three single factor effects, a number of multiple factor "interaction" effects were also significant in contributing to experimental variability. The most important of these interactions, as shown by the ANOVA Tables, F-1, F-2, and F-3, of Appendix F, were the human subject interactions with both liquid type and application/removal method. The subject-liquid type interaction refers to the relative differential retention of different liquids by different subjects. For example, whereas one subject might retain 3 mg/cm^2 more of liquid "L" than of liquid "M," another subject might retain 5 mg/cm^2 more of L than of M.

The subject-application/removal method interaction refers to the relatively different liquid retentions of different subjects for different application/removal processes. For example, whereas one subject, on average, might partially remove 4 mg/cm^2 of the liquid initially retained on his hands, another subject might, for the same liquid, partially remove only 2 mg/cm^2 on

average. Given the natural variability of most experiments involving human subjects, the presence of these interactions was not surprising.

The subject-application/removal differential retention rates might have been further compounded by different liquid types, leading to significant liquid type-application/removal method and subject-liquid type-application/removal method interactions. Thus, for example, all subjects might have, on average, partially removed 5 mg/cm^2 of liquid L but only 3 mg/cm^2 of liquid M, and different subjects might have partially (and fully) removed liquids L and M in different amounts. However, the ANOVA Tables F-1, F-2, and F-3 of Appendix F show that, for this experiment, the latter interactions were not significant.

In fact, the absence of a liquid type-application/removal method interaction guaranteed the desirable result that the retention rates of the separate initial and secondary wipe tests were simply additive. To see this, consider the values of the aggregated means shown in Table 3-3. The differences between successive row (test) means in the table are shown within parentheses. The difference between each pair of these successive differences (by column) is much less than twice the standard error, 0.067, for comparison. Also, the differences between successive column means (shown in braces) are not significant, with an average value equal to the difference of the overall means, 0.19. Thus, when one aggregated over all subjects and liquid types (or, because of the absence of a liquid type-application/ removal method interaction, over subjects only), the resulting liquid retention amounts for the secondary wipe test were equal to the corresponding amounts for the initial wipe test minus an average amount corresponding to that retained after full removal, which in this experiment was approximately 0.2 mg/cm^2.

The amount of liquid retained, therefore, for the initial wipe tests was in all cases greater than that for the secondary wipe tests, the difference being approximately equal to the amount retained after full removal (saturation residual). This suggested that the starting condition of an individual's hands with respect to the liquid in question was an important factor in exposure.

Table 3-3. Aggregated Means[a] of Liquid Amounts Retained on the Surface of Hands (mg/cm^2), Wipe Tests

	Application/removal level					
	Application		Partial removal		Full removal	Overall means
Initial[b,c]	1.64	(1.04)	0.60	(0.36)	0.24	0.83
	[0.21]		[0.17]		[0.18]	[0.19]
Secondary[b,c]	1.43	(1.00)	0.43	(0.37)	0.06	0.64

[a] Aggregated over subjects and liquids.
[b] Standard error of each row mean = 0.033+.
[c] Standard error of each row mean second difference = 2 x 0.033+ = 0.067.

Source: Tables 3-1 and 3-2.

3.2 Immersion Test

The immersion test table of means is shown in Table 3-4. It is obvious from the table that the three factors of experimental subject, liquid type, and application/removal method were all significant sources of variability for the amount of liquid retained on skin. This is confirmed by the factor significance probabilities of the ANOVA Tables F-4 and F-5 of Appendix F. The tables also show the presence of a significant experimental subject-liquid type interaction.

Not surprisingly, substantially more liquid was retained in the immersion test (direct liquid application) than in either the initial or secondary wipe tests (indirect liquid application). Also not surprising was the fact that the liquid with the greatest viscosity (mineral oil) was retained in greater amounts than were the liquids with less viscosity. Those less viscous liquids (cooking oil and bath oil) were retained in statistically not unequal amounts, despite the fact that one (cooking oil) had a viscosity about twice that of the other (bath oil). This was in contrast to the results of the initial and secondary wipe tests where the higher viscosity cooking oil was retained in significantly greater amounts than the lower viscosity bath oil. Any number of hypotheses were available to explain the different results between the two sets of tests.

In the immersion tests, the lower viscosity bath oil may have penetrated skin folds more deeply but also dripped off the wetted hand surface more easily than did the higher viscosity cooking oil. Because of the counter-balancing tendencies of deeper penetration and greater runoff, the result might have been retention of an approximately equal amount of the two oils per unit of apparent (not counting fold areas) skin surface area. However, if the larger effective surface area, because of low viscosity oil penetration, could have been estimated and used in the calculations, then the lower viscosity bath oil might have indeed been found to have a lower retention per unit of skin surface area than the higher viscosity cooking oil.

This situation, for cooking and bath oil, would not apply to the initial and secondary wipe experiments, because in these experiments, the very act of application by wiping might rub both oils into the skin folds equally. Thus, in the wiping experiments, the effective skin surface areas

Table 3-4. Means of Liquid Amounts Retained on the Surface of Hands (mg/cm^2), Immersion Test

	Application/removal[a] replicate means			Application/ removal[a] Row means[b,f]	Overall Row means[c,f]
	Mineral oil	Cooking oil	Bath oil		
Experimental subjects					
A	11.90, 2.58	6.70, 1.93	6.63, 1.49	8.41, 2.00	5.20
B	9.39, 1.53	5.96, 1.27	5.15, 1.70	6.83, 1.50	4.17
C	9.53, 1.48	4.87, 1.15	5.38, 1.23	6.59, 1.29	3.94
D	10.51, 1.41	6.53, 0.97	6.61, 0.93	7.88, 1.10	4.49
Application/removal[a] column means[d,f]	10.33, 1.75	6.02, 1.33	5.94, 1.34	7.43, 1.47	
Overall column means[e,f]	6.04	3.68	3.64		4.45

[a] Table doublet entries = amount retained after application, amount retained after "partial" removal.

[b] Standard error of each application/removal row mean = $\sqrt{(MSE/18)} = 0.112$, where MSE = $^1/_2(0.27 + 0.18) = 0.225$ is the average error mean square from the ANOVA Tables F-4 and F-5 of Appendix F.

[c] Standard error of each overall row mean = $\sqrt{(MSE/36)} = 0.079$.

[d] Standard error of each application/removal column mean = $\sqrt{(MSE/24)} = 0.097$.

[e] Standard error of each overall column mean = $\sqrt{(MSE/48)} = 0.068$.

[f] Standard error of each mean difference = $\sqrt{(2 \times \text{Standard error of each mean})}$.

would be more or less the same for both oils. As a result, the different retentions of the two oils would not be masked.

In any event, if oil viscosity became sufficiently large (as with the mineral oil), then the thicker layering of the oil on skin would far outweigh the decreased penetration effect. Thus, overall, the very high viscosity mineral oil resulted in a larger immersion retention than either the moderate or lower viscosity cooking and bath oils.

This was not true, however, in the wipe experiments where more cooking oil was picked up. While this might seem odd, there may be a plausible explanation. It seems likely that in the immersion experiments, higher viscosity liquids would adhere more to the hands. This seems logical, and it is consistent with everyday experience. In the immersion experiment, when the hand was removed from the container of more viscous liquid, the liquid (which had a greater resistance to flow) would flow slowly back into the container. In the wipe experiment, the more viscous liquid would resist flowing out of the pores of the cloth and thus less liquid would be transferred to the hands. This again is consistent with everyday experience. If a cloth saturated with an extremely viscous substance were picked up, one would expect relatively little liquid to be transferred to the hands. Thus, the wipe experiments would be expected to yield relatively smaller retentions of the high viscosity mineral oil than would the immersion experiments.

4. SUMMARY

This report has presented and analyzed a set of experimental data pertaining to the amount of liquid retained on the surface of hands. The findings of this study are summarized as follows:

- Significant factors affecting liquid retention variability were identified: the individual subject upon whose hands liquid was retained, the type of liquid retained, and the application/removal method associated with the liquid retained.

- Significant combinations, or interactions, of factors affecting retention variability were also identified. The most important such combinations involved the human subjects exposed to the liquids.

  The probable cause of the significance of factor interactions was the subjects themselves. Although controls were applied to render the experimental results as uniform as possible, the variability of the human subjects regarding skin characteristics (e.g., thickness of the stratum corneum, hydration of the stratum corneum, hairiness), self application and removal characteristics, and other characteristics inevitably led to a corresponding significant variability in liquid retention amounts. Put simply, subjects tended to retain different liquids (of different densities, viscosities, etc.) in different amounts. Also, different subjects tended to retain the same liquid in different amounts, primarily because of individual differences associated with physical characteristics and behavioral differences associated with different exposure (application/removal) practices.

- Of the various experimental results reported herein, most were affected somewhat by technique. For example, initial exposure from a cloth would depend on the subjects' handling of the cloth. Any measurement requiring a partial "removal" would be highly technique-sensitive and very subject-dependent.

- The measurements that were believed to be least technique-sensitive were (1) the amount adhering to the hands after immersion and (2) the amount that could not be removed with a clean dry cloth (i.e., the amount remaining in the wipe experiments after the full removal).

- For the technique-sensitive measurements, the observation that the identity of the subject had an effect on the results was not surprising, and it does not indicate real differences in different people's potential for exposure. However, these differences were also observed for measurements that were not technique-sensitive, and this indicates real differences in the exposure potential for different people. Presumably, these differences related to some physical characteristics of the people.

The experimental results of the project are summarized in Tables 4-1 and 4-2. Table 4- presents the mean amounts of liquid retained on skin for each liquid and eacl application/removal method used in the experiment. Table 4-2 lists the mean film thickness o liquid on skin for the same sets of variables, calculated using Equation (2). Because th densities of the liquids used in the experiment were roughly equivalent, the pattern of value obtained for film thickness is similar to that observed for liquid retention. The secondary wip film thicknesses were consistently less than initial wipe film thicknesses, presumably becaus of skin saturation with liquid from the initial wipe. Also, partial and full removal filn thicknesses were uniformly less than application film thicknesses. Finally, immersion filn thicknesses were much greater than wipe film thicknesses, with high viscosity mineral oi immersion film thicknesses being the greatest of all those calculated.

It was not possible within the scope of this project to collect liquid retention data fo more than a few experimental subjects, liquid types, and application/removal methods. Thus, sufficient data did not exist to perform an analysis of covariance study to quantify th relationship between liquid retention amount, viscosity of liquid retained, and other experimental variables. The limited results of this study are insufficient to quantify representative film thicknesses corresponding to liquid viscosities; however, the results can be used as rough, order-of-magnitude values in screening level exposure calculations. In order to obtai representative values for film thickness, further method development would be needed, requiring additional experiments using a greater number of individuals and wider range of liquid type than were possible in the experiments discussed herein.

Table 4-1. Means of Liquid Amounts Retained on the Surface of Hands (mg/cm^2), All Tests

	Initial wipe test[a,c,e]	Secondary wipe test[a,c,e]	Immersion test[b,d,e]
Mineral oil	1.36, 0.54, 0.24	1.22, 0.41, 0.05	10.33, 1.75
Cooking oil	2.07, 0.75, 0.32	1.72, 0.48, 0.06	6.02, 1.33
Bath oil	1.49, 0.51, 0.17	1.34, 0.41, 0.07	5.94, 1.34

[a] Table triplet entries = amount retained after application, amount retained after partial removal, amount retained after full removal.

[b] Table doublet entries = amount retained after application, amount retained after partial removal.

[c] Standard error of each mean = 0.058.

[d] Standard error of each mean = 0.097.

[e] Standard error of each mean sum or difference = $\sqrt{2}$ x Standard error of each mean.

Source: Tables 3-1, 3-2, and 3-4.

Table 4-2. Means of Liquid Film Thickness on the Surface of Hands (10^{-3} cm). All Tests

	Initial wipe test[a]	Secondary wipe test[a]	Immersion test[b]
Mineral oil	1.56, 0.62, 0.27	1.40, 0.47, 0.06	11.87, 2.00
Cooking oil	2.25, 0.82, 0.34	1.87, 0.52, 0.07	6.55, 1.46
Bath oil	1.74, 0.59, 0.20	1.56, 0.48, 0.08	6.90, 1.55

[a] Table triplet entries = film thickness after application, film thickness after partial removal, film thickness after full removal.

[b] Table doublet entries = film thickness after application, film thickness after partial removal.

Source: Tables 2-2 and 4-1.

APPENDIX A

Documentation of Compliance with 45 CFR 46
Protection of Human Subjects

Versar INC.

April 26, 1983

Dr. R. C. Backus
Office for Protection
from Research Risks
National Institutes of Health
Bethesda, MD 20205

Dear Dr. Backus:

I am enclosing the following material pursuant to your letter of April 5, 1983 and our subsequent phone discussions.

1) Research Work Plan
2) Human Subject Consent Form and Research Summary
3) Compliance Statement
4) Minutes of the IRB meeting

I trust that this information will be sufficient for your evaluation of our proposed use of human subjects in research. Please do not hesitate to call me at (703) 642-6759 should any questions arise. I appreciate your attention to this matter and look forward to your response.

Sincerely,
VERSAR INC.

Thomas C. Voice
Staff Research Engineer
Applied Chemistry Division

TCV/mb

6850 VERSAR CENTER • P.O. BOX 1549 • SPRINGFIELD, VIRGINIA 22151 • TELEPHONE: (703) 750-3000 • TELEX: 901125

VERSAR INC.

Human Subject Consent Form

Project Title: Retention of Liquids on Hands
Project Number: 715.21
Name of Project Director: Gayaneh Contos
Name of Principal Investigator: Thomas C. Voice

Name of Subject: _____ Telephone: _____
Address of Subject: _____
_____
_____

I consent to my (the subject's) participation in this resear project and declare that I have been given:

1. an explanation of why the research is being done, how it wi be done, what is being tried for the first time and how long is expected to take;

2. a warning about any risks or discomfort to be expected;

3. a description of any benefits to be expected;

4. the name of a person who will answer questions about th research, the rights of a person in a research project or i case he or she is injured;

5. notice that it is not necessary to take part in the researc and that one can drop out at any time without being penalize in any way;

6. a promise that, to the extent permitted by law, any informatio about me (the subject) will be kept confidential and used onl for medical or research purposes and that my (the subject's) name will not be used.

I understand that, if I (the subject) am (is) injured because of the way this research is done, I (the subject) will not be compensated but I (the subject) can receive emergency care at one of the local hospitals.

Signature of Participant or Legal Representative: _____ Date: _____

Signature of Auditor Witness: _____ Date: _____

Relationship: _____

This is to affirm that the basic elements of informed consent as described above, and additional elements, if any, have been presented to the subject or his/her legally authorized representative in accordance with the attached summary. It is also affirmed that this research project and all relevant documentation, including this form and attached summary have been presented to and approved by an Institutional Review Board conforming to the requirements of Health and Human Services regulations 45 CFR 46, "Protection of Human Subjects."

Signature of Official Obtaining Consent: _____ Date: _____

Signature of Auditor Witness: _____ Date: _____

Research Summary

The proposed research project "Retention of Liquids by Hands" is designed to quantify the amount of various classes of liquids that will be retained by human hands under controlled exposure conditions. It is the ultimate goal of this work to aid in the assessment of risk to individuals contacting liquids which may be contaminated by toxic substances. This research, however, involves only harmless, commonly available liquids.

In the course of this research you will be asked to immerse your hands in two of the liquids listed below, which will be at room temperature.

1. heavy mineral oil
2. cooking oil
3. water-soluble oil (Alpha-Keri, a dry skin product)
4. oil/water emulsion
5. water
6. water/isopropyl alcohol.

The liquid retained by your hands will be removed by wiping with a gauze pad, either dry or wetted with isopropyl alcohol or other non-toxic solvent. The liquid recovered will then be measured. You will also be asked to have the area of your hand measured. This will be accomplished by immersing your hand in a water/food coloring solution and then blotting a piece of paper or by tracing the outline of your hand. Additional measurements with a ruler will be made. The entire procedure should take about 30 minutes.

You are asked not to participate in this study if you have any visible cuts or sores on your hands.

No additional risks, above those normally encountered in daily activities, or any discomfort are expected as a result of this study.

Participation in this study is entirely voluntary and you can drop out of the study at any time without penalty of any sort.

It is anticipated that this research will aid in the assessment of risk to those individuals who may be inadvertently or unknowingly exposed to toxic substances.

Any questions regarding this work should be directed to Dr. Thomas C. Voice at (703) 750-3000.

Versar inc.

RETENTION OF LIQUIDS ON THE SURFACE OF HANDS

WORK PLAN
April 25, 1983

This document proposes an experimental work plan to evaluate the amount of liquid that can be retained on the surface of human hands under different exposure scenarios. Since this value is obviously dependent upon the amount of liquid contacting the hands, an upper bound will be determined by immersing the hands in the liquid of interest, all of which will be at room temperature. Additional test procedures will assess the amount retained under simulated exposure conditions. Several different liquids will be evaluated and an attempt will be made to correlate to the liquid viscosity.

The following liquids have been selected for investigation on the basis of apparent bulk properties:

1. heavy mineral oil
2. light cooking oil
3. water soluble oil
4. oil/water emulsion (50:50)
5. water
6. water/iso-propyl alcohol (50:50)

Viscosity and density measurements will be made on each liquid.

Individuals with visible cuts or sores on their hands will be eliminated from consideration as research subjects.

MAXIMUM EXPOSURE SCENARIO

To evaluate the retention capacity of hands the following experimental procedure will be conducted in triplicate for each liquid:

1. A volunteer's hand will be immersed in a container of liquid up to a mark that has been placed at the wrist.

2. The hand will be removed and allowed to drip for a predetermined length of time to remove the excess liquid. Alternatively, a gentle shake of the hand may be required to remove the excess liquid expediently.

3. The liquid will be absorbed from the hand by wiping completely with surgical gauze pads that have been pre-weighed. The pads may have to be wetted with a solvent (e.g., iso-propyl alcohol or other similar non-toxic solvent) to remove the oils. The pads will be re-weighed to determine the mass of liquid collected. If a solvent is used, the pad will be extracted, the solvent evaporated, and the residue will be weighed.

4. An attempt will be made to quantify the amount of liquid picked-up by each volunteer's hand by weighing the liquid container before and after immersion.

5. An attempt will be made to directly measure the film thickness at various points on a volunteer's hand using non-invasive techniques.

6. The surface area of each volunteer's hand will be approximated by tracing the outline of the hand or by measuring a blot obtained using a water soluble dye and directly measuring the thickness of the hand. The total exposed area is thus:

$$\frac{(\text{area of blot}) \times 2 + (\text{"perimeter" of blot}) \times (\text{thickness})}{\text{total surface area of hand}}$$

The measurements of liquid mass retained by each hand will be normalized with respect to surface area. If desired, a uniform film thickness can be calculated using the liquid density. A least-squares analysis will be used to determine the extent of any correlation between normalized liquid retention and viscosity.

OTHER EXPOSURE SCENARIOS

Using identical procedures as those outlined above, the following additional scenarios will be evaluated:

1. immersion followed by casual wiping with a clean rag.
2. immersion followed by thorough wiping with a clean rag.
3. wiping up of a liquid spill with a clean rag.

VERSAR INC.

Assurance of Compliance with HHS Regulations for
Protection of Human Research Subjects

PART 1

Versar Inc. hereinafter known as the "institution," hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended on January 26, 1981) as specified below.

I. Statement of Principles and Policies

A. Ethical Principles

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report,"). In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all applicable research.

B. Institutional Policy

1. Except for research in which the only involvement of human subjects is in one or more of the categories exempted or waived under 45 CFR 46.101(b)(1-5) or 46.10(e) of the HHS regulations, this policy is applicable to all research involving human subjects, and all other activities which even in part involve such research, if either:

   a. the research is sponsored by this institution, or
   b. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
   c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
   d. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

2. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this policy.

3. This institution assures that before human subjects are involved in research covered by this policy, proper consideration will be given to:

   a. the risks to the subjects,
   b. the anticipated benefits to the subjects and others,
   c. the importance of the knowledge that may reasonably be expected to result, and
   d. the informed consent process to be employed.

4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy.

5. This institution bears full responsibility for complying with federal, state or local laws as they may relate to research covered by this policy.

6. This institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

7. This institution will exercise appropriate administrative overview carried out at least annually to insure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

8. This institution will consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children, individuals institutionalized as mentally disabled, other potentially vulnerable groups and human <u>in vitro</u> fertilization.

9. This institution shall provide each individual at the institution conducting or reviewing human subject research (e.g., research investigators, department heads, research administrators, research reviewers) with a copy of this statement of ethical principles and policy (Part 1, I.A & B.).

PART 2

In regard to the project entitled Retention of Liquids on Hands, Project number 715.21, submitted on behalf of Thomas C. Voice, this institution has complied and will continue to comply with the requirements of 45 CFR 46 as specified below.

I. IRB Review

A. The convened IRB reviewed and approved the above project.

B. The IRB has determined, in accordance with the criteria found at 45 CFR 46.111, that human research subjects' protections are adequate.

C. The IRB has determined that legally effective informed consent (copy of document attached) will be obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 46.117.

D. The IRB shall review, and have the authority to approve, require modification in, or disapprove changes proposed in this research activity.

E. The next scheduled meeting of the IRB for review of this activity will be May 19, 1983. The IRB may be called into an interim review session by the Chairperson at the request of any member, an institutional official, or the project director to consider any matter concerned with the rights and welfare of any subject.

F. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 45 CFR 46.115.

G. The IRB shall report promptly to institutional officials and the Office for Protection from Research Risks (OPRR):

1. any serious or continuing noncompliance by investigators with the requirements of the IRB, and
2. any suspension or termination of IRB approval.

H. The IRB shall report promptly to institutional officials any information received concerning:

1. injuries to human subjects, and
2. unanticipated problems involving risks to subjects or others.
3. any changes in this research activity which are reviewed and approved by the IRB.

II. Research Investigator Reporting Responsibilities

A. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

B. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

III. Institutional Responsibilities

A. this institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and recordkeeping duties.

B. This institution shall report promptly to the OPRR:

1. injuries to human subjects,
2. unanticipated problems involving risks to subjects or others, and
3. any changes in this research activity which are reviewed and approved by the IRB and this institution.

C. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project entitled Retention of Liquids on Hands.

D. In accordance with the compositional requirements of section 46.107 of 45 CFR 46, this institution has established an IRB as listed in the following roster. This IRB is responsible for the initial and continuing review of this activity and will observe the quorum requirements of 46.108.

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

IRB NAME AND NUMBER: ____________________

MEMBER NAME FIRST M.I. LAST	HIGHEST DEGREES EARNED	SCIENTIFIC SPECIALITY	AFFILIATION WITH INSTITUTION	ADDRESS AND PHONE NUMBER- CHAIRPERSON ONLY
* Charles W. Carter	Ph.D.	Environmental Chemistry	Employee	6850 Versar Center P.O. Box 1549 Springfield, Virginia 22151
Pamela A. Hillis	B.S.Ch.E.	Chemical Engineering	Employee	
Mark T. Carkhuff	B.A.	Biology	Employee	
Angela N. Murray	H.S. & Bus Sch	None	Employee	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Rev. Jordan E. Dickinson	M. Divinity	None	None	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
**				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
NV				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

* Denotes Chairperson
** Denotes Alternates
NV Denotes Non-voting Members

PART 3

Institutional endorsement and HHS approval
regarding this assurance and the project
titled Retention of Liquids on Hands,
Project number 715.21.

I. I certify that the above project was reviewed and approved by th Versar Inc. IRB in accordance with the requirements of Part 46 Title 45 of the Code of Federal Regulations and this assurance o compliance on April 21, 1983.

IRB Chairperson
Signature: _____ Date: 4-27-83
Name: Charles W. Carter
Address: 6850 Versar Center
P.O. Box 1549
Springfield, Virginia 22151

Phone: (703) 750-3000

II. I certify that this institution endorses the above project anc abides by the principles, policies, and procedures of PARTS 1 and 2 of this assurance of compliance.

Authorized Institutional Official (primary contact)
Signature: _____ Date: 4/26/83
Name: Thomas C. Voice
Title: Staff Research Engineer
Address: 6850 Versar Center
P.O. Box 1549
Springfield, Virginia 22151

Phone: (703) 750-3000

****

-SPACE BELOW FOR HHS-

III. All parts of this assurance are in compliance with the requirements of Part 46, Title 45 of the Code of Federal Regulations.

HHS Approving Official
Signature: _____ Date: _____
Name: _____
Title: _____
Address: _____

Phone: _____

Versar Inc.

Versar Inc. Institutional Review Board

Minutes

Convened: Versar Inc. 4:00pm 21 April 1983

Discussed and made recommendations for changes on certain points within the workplan form entitled "Retention of Liquids on the Surface of Hands." Scheduled next meeting for 4:00pm 19 May 1983.

Adjourned: 5:00pm 21 April 1983

Present:

IRB Members
Charles W. Carter, Chairman
Mark T. Carkhuff, Secretary
Angela N. Murray
Pamela A. Hillis
Jordan E. Dickinson

Others
Thomas C. Voice

Mark T. Carkhuff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Servi

National Institutes o
Bethesda, Maryland

May 5, 1983

Michael A. Callahan, Chief
Exposure Assessment Branch
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, D. C. 20460

S 5156-01 (EPA)

Dear Mr. Callahan:

We have reviewed and enclose herewith the assurance document received from Versar, Inc. dated April 26, for the EPA project on "Retention of Liquids on the Surface of Hands", Dr. Thomas C. Voice, project Director.

To assist in your determination of acceptability for conformance of the assurance with the requirements of HHS regulation 45 CFR 46 on protection of human reseach subjects by the Environmental Protection Agency we offer the following comments.

We note that test materials may include a "water soluble dye" without specification of composition, source or concentration. Since some water soluble dyes are toxic, such tests should be limited to dyes approved by the FDA for coloring foods, drugs or cosmetics or similar uses. Furthermore, if dyes are to be used in any tests with subjects, the consent procedures should include such information.

Even though the risks in these tests appear to be remote, HHS would request the addition of at least one IRB member or consultant to the IRB who (preferably) is a medical specialist in dermatology, or who has scientific competency (Ph.D. or equivalent) in physiology, biochemistry, pharmacology or toxicology.

These matters have been discussed with Dr. Voice and revised assurance documents will be sent directly to you. A copy of regulation 45 CFR 46 is enclosed. Annual certification of IRB review to EPA should be made, if applicable; several copies of form HHS 596 that may be used for certification are also enclosed. If you have questions or feel we can assist you further, let us know.

Sincerely,

Charles R. Mackay

Charles R. Mackay, Ph.D.
Deputy Director,
Office for Protection from
Reseach Risks

cc: Dr. Thomas C. Voice, Versar, Inc.

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

MAY 25 1983

OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Project on "Retention of Liquids on the Surface of Hands"

FROM: Roger S. Cortesi
Acting Director
Office of Health Research (RD-683)

TO: Michael A. Callahan
Project Officer and Chief
Exposure Assessment Branch (TS-798)

We in the Office of Health Research have reviewed this study and find it to be in compliance with EPA Order 1000.17, Policy and Procedures for Protection of Human Subjects in Research, assuming incorporation of the comments in Dr. Mackay's letter to you of May 5, 1983.

cc: Patricia Thomaier (OA/CMD/RTP)

Versar INC.

June 17, 1983

Dr. Neil Jurinski
Nuchemco Inc.
9321 Rain Tree Road
Burke, Virginia 22015

Dear Dr. Jurinski:

I am enclosing the following material pursuant to our telephone conversation on June 15, 1983, regarding your review of our use of human subjects in the research study "Retention of Liquids on the Surface of Hands."

1) Research Work Plan
2) Human Subject Consent Form and Research Summary
3) Compliance Statement
4) Minutes of IRB Meeting
5) 45 CFR 46 Protection of Human Subjects
6) May 5, 1983 letter from Dr. Mackay of NIH reviewing the project
7) May 25, 1983 memorandum from R.S. Cortesi of EPA reviewing the project.

All of the methodology changes suggested in the review process have been incorporated into the work plan at this time. I have been informed that a brief written review by you will be sufficient to address Dr. Mackay's request for an additional IRB member.

Your comments should be sent directly to:

Michael A. Callanhan, Chief
Exposure Assessment Branch
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Your invoice to Versar should reference project 715.56.

Please do not hestitate to call me at 642-6759 should any question arise. Thank you, in advance, for your assistance in this matter.

Sincerely,

VERSAR INC.

Thomas C. Voice, Ph.D.
Staff Research Engineer
Applied Chemistry Division

NU CHEMCO, INC.

INDUSTRIAL HYGIENE, ENVIRONMENTAL, AND CHEMICAL SERVIC

24 June 1983

Michael A. Callanhan, Chief
Exposure Assessment Branch
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Versar Project "Retention of Liquids on the Surface of Hands"

Dear Mr. Callanhan:

I have been requested by Dr. Thomas C. Voice, Principal Investigator, Versar, Inc., to provide assistance to the Institutional Review Board of Versar (Springfield, VA). I have enclosed with this letter a copy of my brief resume for your files. You will see that I am active in the field of health effects of chemical materials on humans, and employed full-time in the areas of toxicology and industrial hygiene. My comments relative to the proposed experimental work of this project follow.

A work plan of April 25, 1983, entitled "RETENTION OF LIQUIDS ON THE SURFACE OF HANDS" was reviewed from the context of whether the proposed work plan posed significant identifiable health risks to the research participants, amd whether the work was in any way inconsistent with the intent of the governing regulations, 45 CFR 46. Also reviewed in addition to the work plan and the regulations, were the documents entilted VERSAR INC. Human Subject Consent Form (undated), Research Summary (undated), and VERSAR INC. Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects.

The work plan indicates that test subjects hands will be immersed to the wrists in several liquids. The liquids proposed for use [heavy mineral oil, light cooking oil, watersoluble oil, oil/water emulsion (50:50), water, water/isopropyl alcohol (50:50)] pose no significant health hazard to the test participants. Other test procedures involve physical measurements similarly posing no hazard to the individuals. There appears to be no cause for concern regarding any toxic effects that will result from the conduct of the stipulated tasks of the work plan.

One comment is made regarding the Human Subject Consent Form. It would be appropriate to include either the age or date of birth of subjects to provide documentation that the subjects are indeed over the age of 18. I have no other concerns regarding the conduct of these tests.

Sincerely,

Neil B. Jurinski, Ph.D., C.I.H.
President

encl.

9321 RAINTREE ROAD • BURKE, VIRGINIA 22015 • (703) 978-0642

NEIL B. JURINSKI, Ph.D.
Certified Industrial Hygienist
9321 Raintree Road
Burke, VA 22015
703-978-0642

EDUCATION: B.S., State University of New York, Albany, New York, Chemistry, 1960

Ph.D., University of Mississippi, Oxford, Mississippi, Physical Chemistry, 19

PROFESSIONAL CERTIFICATION: Certified Industrial Hygienist, Comprehensive Practice, American Board c Industrial Hygiene

Certified Hazard Control Manager, Master Level
International Hazard Control Manager Certification Board

PROFESSIONAL EXPERIENCE:

Private Consultant: President, NuChemCo, Inc., Burke, VA, a small business consulting service company, specializing in chemical hazard control problems. Provides technic consulting services for environmental control, industrial hygiene and toxi chemical handling and disposal programs. Regular services include a full rang of industrial hygiene field surveys, development of control techniques fo chemical carcinogens, and external audits and critiques of on-going health an safety programs.

Prior Activities:

- Participated in EPA Emergency Response Team efforts for monitoring episode of airborne toxicants by providing health and safety guidance to team member
- Developed and implemented a comprehensive Health and Safety Program fo multi-site operations involving chemical carcinogens, addressing both occupa tional and environmental control.
- Developed a system for assessing the extent of worker hazard in laborator facilities.
- Conducted field survey operations to implement industrial hygiene program
- Participated in defining allowable exposure standards for chemical substance prior to promulgation of OSHA regulations.
- Developed Procedures Manual and Personnel Training Program for support c industrial hygiene field workers.
- Supervised analytical chemistry laboratory performing environmental an industrial hygiene chemistry. Secured AIHA accreditation for laboratory.
- Developed sampling and analysis procedures for trace level organic and inorgani materials.
- Provided consultation on sampling, analysis and method development in area of industrial hygiene, air and water pollution, solid waste disposal, toxicology biochemistry and data quality.
- Developed system description document for laboratory automation via on-lin data collection to minicomputer CPU, to also handle data processing and repo generation.

- Conducted and participated in training courses in areas of industrial hygiene and in environmental chemistry.
- Taught graduate level courses in aspects of spectroscopy.
- Supervised graduate research and thesis programs of Ph.D. and M.S. chemists.
- Performed chemical synthesis and surface modification of inorganic products.
- Established and supervised applications laboratory in aspects of material flow conditioning.
- Developed analysis methods and studied kinetics and equilibrium of nitroaromatic explosive compounds in regard to their chemical breakdown products.
- Supervised analytical spectroscopy laboratory supporting research program of a major photo-products company.

PROFESSIONAL MEMBERSHIPS

American Industrial Hygiene Association
American Academy of Industrial Hygiene
American Chemical Society
The Chemical Society (London)
Sigma Xi
American College of Toxicology
American Society of Safety Engineers

APPENDIX B

Method for Determining the Surface Area of Hands

EXPERIMENTAL MATERIALS

1. Small diameter tracing pen and standard 8-1/2 x 11 white paper
2. Calipers
3. Summa Graphics Micro Grid Model 68XX27 Digitizer

EXPERIMENTAL PROCEDURE

1. Mark opposite sides of hand (wrist) for tracing (these marks estimate the amount of hand exposed to liquids).

2. Place hand - palm down, fingers spread - on paper.

3. With pen on paper, trace around perimeter of hand and fingers between opposite wrist marks.

4. Measure perimeter trace, p, with digitizer. The results of these measurements are shown in Table B-1.

5. Connect side marks with straight line trace.

6. Measure area, S, within closed trace with digitizer. The results of these measurements are shown in Table B-1.

7. With caliper, measure hand thickness at nine locations: three between the wrist marks, three midway between the wrist and first knuckles, and one each on the index, ring, and forefingers between the first and second knuckles. The results of these measurements are shown in Table B-2.

8. Compute average, t, of the nine hand thickness measurements. The results of these computations are shown in Table B-2.

QUALITY ASSURANCE

Slightly different experimental procedures were also used to measure subjects' hands, but all procedures gave surface areas, SA, which differed by no more than the logical error ($\pm$ about 5 percent) contained in the cookie-cutter approximation. Thus, all hand measurement procedures were internally consistent, yielding surface areas the same ($\pm$ about 5 percent) as those reported here.

Table B-1. Hand Perimeter and Area Measurements

	Parameter, p (cm)[1]		Area, S (cm^2)[1]	
	left	right	left	right
Subject:				
A	106	105	170	164
B	90	88	115	103
C	98	99	148	150
D	107	107	168	163

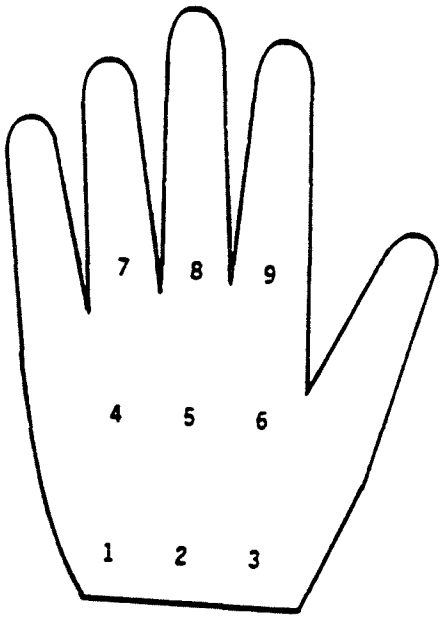
[1]Total hand surface area, SA (cm^2) = 2•S + p•t, where p and S are measured as in the table, and t(cm), the average hand thickness, is measured as in Table B-2.

Table B-2. Hand Thickness Measurements

	Thickness, t (cm) Measurement location[1]									
	1	2	3	4	5	6	7	8	9	Average value
Subject/hand:										
A/left	3.5	3.7	2.8	3.7	3.7	3.2	1.4	1.5	1.4	2.8
right	3.4	3.6	3.5	3.2	3.5	3.3	1.3	1.4	1.1	2.7
B/left	3.0	3.2	2.2	2.2	2.5	2.1	1.2	1.4	1.2	2.1
right	2.9	3.0	2.3	2.7	2.5	2.1	1.3	1.3	1.1	2.1
C/left	3.0	3.3	3.0	3.0	3.0	2.4	1.5	1.6	1.4	2.5
right	2.6	3.2	3.5	3.5	3.0	2.5	1.5	1.5	1.3	2.5
D/left	3.4	3.7	2.6	3.3	3.2	2.5	1.3	1.4	1.3	2.5
right	2.7	3.7	3.8	4.1	4.0	3.2	1.3	1.2	1.5	2.8

[1] Measurement locations:

+ mirror image for right hand



APPENDIX C

Liquid Density and Viscosity Measurements

To ensure uniformity of liquid density and viscosity measurements between the two tasks comprising the experiment:

- The density of each liquid was measured at room temperature by Gascoyne Laboratories using a Bingham Pyncnameter following ASTM Method D4052-86, and
- The viscosity of each liquid was measured at room temperature by Gascoyne Laboratories using a Cannon-Fenske viscometer following ASTM method D445.

The results of these measurements are shown in Tables C-1, C-2, and C-3.

Table C-1. Mineral Oil

Gascoyne Laboratories, Inc.

Baltimore, MD 21224-6697

BA
(3

SA
(3

REPORT OF ANALYSIS

Report No. 88-06-133

Report Date: June 15, 1988

Report To: Versar, Inc.

Sample I.D. Mineral Oil

Parameter	Results	Detection Limits	Method	Analyst	Date Compl
Viscosity @ 23° C	160.2 cSt	0.1	ASTM D445	DM	06/09
Specific Gravity @ 24.5° C	0.870	0.001	ASTM D4052-86	DM	06/10

Irving M. Kipnis
Laboratory Director
Irving M. Kipnis Ph.

Gascoyne Laboratories, Inc.
Baltimore, MD 21224-6697

BALTIMORE, M
(301) 285-851
SALISBURY MD
(301) 543-105

REPORT OF ANALYSIS

Report No. 88-06-133 Report Date: June 15, 1988

Report To: Versar, Inc. Page: 2 of 3

Sample I.D. Cooking Oil

Parameter	Results	Detection Limits	Method	Analyst	Date Test Completed
Viscosity @ 23° C	59.2 cSt	0.1	ASTM D445	DM	06/09/88
Specific Gravity @ 24.5° C	0.920	0.001	ASTM D4052-86	DM	06/10/88

Laboratory Director

Table C-3. Bath Oil

Gascoyne Laboratories, Inc.

Baltimore, MD 21224-6697

BAL
(30

SAL
(30

REPORT OF ANALYSIS

Report No. 88-06-133 Report Date: June 15, 1988

Report To: Versar, Inc. Page: 3 of 3

Sample I.D. Bath Oil

Parameter	Results	Detection Limits	Method	Analyst	Date Comple
Viscosity @ 23° C	33.3 cSt	0.1	ASTM D445	DM	06/09/
Specific Gravity @ 24.5° C	0.861	0.001	ASTM D4052-86	DM	06/10/

Irene M. Kyriss
Laboratory Director

APPENDIX D

Liquid Application/Removal Procedures

EXPERIMENTAL MATERIALS

1. Experimental liquids: mineral oil, cooking oil, bath oil

2. One-gallon wide-mouth jar

3. PVC gloves

4. 100 percent cotton cloths and plastic holding cups

5. Mettler PC440 laboratory balance (0.01 g accuracy)

6. Liquid hand wash soap (manufactured by Standard Sanitation Systems, Inc.)

7. Water soluble marker

MATERIAL PREPARATION

1. Fill a clean 1-gallon wide-mouth jar approximately half full of the liquid to be studied.

2. Calibrate Mettler PC440 balance with class S weights.

3. Place three clean cotton cloths into separate plastic cups and tare weigh using the balance. The cups should be labeled and the tare weights recorded. The cloths should be designated as follows:

   a. Application
   b. Partial Removal
   c. Full Removal

4. Record laboratory relative humidity.

INITIAL WIPE TEST PROCEDURE

1. Fifteen minutes before testing, wash subject's hands with liquid soap for 30 seconds. Thoroughly rinse hands to remove all soap residue and then dry hands.

2. Mark front and back of subject wrists (where hand begins) with water soluble marker.

3. Wearing PVC gloves, immerse the cloth from the cup labeled "application" into the liquid and wring the cloth out only enough to stop the dripping. Return the cloth to the cup and weigh. Record this weight on the data sheet.

4. Immediately instruct the subject to rub the saturated cloth over both hands, front and back up to the mark, for 30 seconds. At the end of this time, have the subject replace

the cloth in the cup and allow any drips from his/her hands to fall into the cup for 30 seconds.

5. Reweigh the application cloth.

6. Have the subject wipe his/her hands lightly for 5 seconds (superficially) with the partial removal cloth and place it back in the cup.

7. Immediately weigh the partial removal cloth and record the weight.

8. Have the subject wipe their hands as thoroughly and completely as possible within 10 seconds removing as much liquid as possible, using the full removal cloth. Have the subject replace the cloth into the cup.

9. Immediately weigh the full removal cloth and record the weight.

SECONDARY WIPE TEST PROCEDURE

1. Repeat steps 2 through 9 of the initial wipe test procedure immediately after the initial wipe test. Record measurements as "secondary" wipe test measurements.

IMMERSION TEST PROCEDURE

1. Same as step 1 for initial wipe test procedure.

2. Same as step 2 for initial wipe test procedure.

3. Have the subject immerse one hand in liquid up to a previously marked spot on the wrist for 10 seconds. Withdraw the hand and allow it to drip for 30 seconds (1 minute for cooking oil).

4. Have the subject wipe the hand lightly and quickly with the partial removal cloth for 15 seconds while trying to avoid getting liquid on the other hand. Have the subject return the cloth to the cup.

5. Immediately weigh the partial removal cloth and record the weight.

6. Immediately have the subject wipe the hand thoroughly and completely with the full removal cloth for 10 seconds, again trying to avoid getting any oil on the other hand. Have subject return cloth to cup.

7. Immediately weigh the full removal cloth and record the weight.

QUALITY ASSURANCE

Testing was limited to only one oil per day for each subject to eliminate any additive effects that could have been introduced by potentially saturating the skin with the test oils. The relative humidity was recorded daily to account for any differences in measurements that could be related to the humidity, such as the absorption of water by cotton.

Weighing errors were minimized by calibrating the balance with class S weights before each day's experiments, and cloth absorption differences were minimized by obtaining the cloths from a single source. Subject application/removal technique differences were minimized by giving clear verbal and written instructions to each participant before beginning experiments, and subject hand condition differences were minimized by using a standard hand washing procedure before each initial wipe and immersion test.

APPENDIX E

Data Tables: Amount of Liquid Retained on the Surface of Hands, Wipe and Immersion Tests

Table E-1. Amount of Liquid Retained on the Surface of Hands (mg/cm^2), Wipe Tests [1,2]

	Mineral oil						Cooking oil						Bath oil					
	Initial wipe			Secondary wipe			Initial wipe			Secondary wipe			Initial wipe			Secondary wipe		
Experimental subjects:																		
A	1.47,	0.63,	1.41	1.36,	0.61,	0.15	4.35,	1.46,	0.92	3.37,	0.86,	0.61	2.00,	0.64,	0.30	1.59,	0.43,	0.05
	1.66,	0.86,	0.40	1.34,	0.40,	0.02	3.07,	0.85,	0.52	2.69,	0.76,	0.06	1.89,	0.58,	0.06	1.71,	0.30,	0.04
	1.57,	0.75,	0.41	1.28,	0.29,	-0.07	2.93,	1.42,	0.86	2.14,	0.30,	-0.36	1.99,	0.78,	0.37	1.52,	0.46,	-0.06
	1.73,	0.79,	0.13	1.36,	0.54,	0.03	1.86,	0.88,	0.23	1.60,	0.68,	-0.02	1.83,	0.87,	0.16	1.43,	0.55,	0.02
B	1.32,	0.56,	0.30	1.09,	0.47,	0.23	1.94,	0.61,	0.27	1.61,	0.49,	0.17	1.73,	0.67,	0.38	1.32,	0.31,	0.14
	1.27,	0.47,	0.26	1.16,	0.46,	0.12	1.52,	0.45,	0.15	1.48,	0.48,	0.06	1.56,	0.49,	0.31	1.84,	0.79,	0.51
	1.22,	0.49,	0.31	1.21,	0.44,	0.16	1.77,	0.65,	0.21	1.32,	0.41,	0.03	1.54,	0.58,	0.31	1.46,	0.35,	0.14
	1.32,	0.77,	0.10	1.33,	0.71,	0.10	1.92,	1.03,	0.17	1.50,	0.81,	0.06	1.52,	0.89,	0.16	1.50,	0.77,	0.15
C	1.26,	0.29,	0.13	1.12,	0.12,	-0.03	2.31,	0.77,	0.56	1.95,	0.49,	0.62	1.15,	0.27,	0.17	1.02,	0.22,	0.01
	1.11,	0.31,	0.12	1.02,	0.13,	-0.02	2.56,	0.77,	0.44	1.84,	0.32,	-0.09	1.14,	0.25,	0.12	1.14,	0.26,	0.11
	1.02,	0.24,	0.08	1.05,	0.20,	0.05	2.25,	0.56,	0.26	1.99,	0.34,	0.01	1.16,	0.28,	0.11	1.12,	0.25,	0.07
	1.41,	0.70,	0.11	1.25,	0.62,	0.03	1.55,	0.61,	0.17	1.31,	0.51,	0.02	1.49,	0.69,	0.13	1.19,	0.48,	-0.04
D	1.78,	0.84,	0.24	1.37,	0.40,	0.03	1.25,	0.46,	0.14	1.09,	0.25,	-0.11	0.99,	0.34,	0.08	0.97,	0.27,	0.13
	0.87,	-0.02,	-0.38	1.17,	0.40,	-0.02	1.13,	0.34,	0.08	1.09,	0.25,	-0.10	1.01,	0.32,	0.10	1.00,	0.29,	0.02
	1.19,	0.30,	0.10	1.14,	0.30,	0.08	1.05,	0.32,	0.05	0.97,	0.22,	-0.11	1.05,	0.34,	-0.02	0.97,	0.23,	-0.03
	1.49,	0.69,	0.14	1.23,	0.50,	-0.07	1.65,	0.74,	0.06	1.48,	0.53,	-0.06	1.82,	0.17,	0.00	1.64,	0.59,	-0.12

[1] Table triplet entries = amount retained after application, amount retained after partial removal, amount retained after full removal.

[2] The first three replicates for each subject, oil, and test are from experiment three measrements; the last replicate is from experiment two measurements.

Table E-2. Amount of Liquid Retained on the Surface of Hands (mg/cm^2), Immersion Test[1,2]

	Mineral oil	Cooking oil	Bath oil
Experimental subjects:			
A	11.92, 1.98	6.42, 1.32	6.60, 0.75
	12.46, 1.58	7.20, 1.61	6.61, 0.88
	12.50, 1.82	6.75, 1.62	6.65, 0.57
	11.35, 3.10	6.68, 2.64	6.17, 1.68
	11.22, 3.65	6.70, 2.41	6.64, 2.26
	11.97, 3.37	6.68, 2.22	7.11, 2.79
B	9.17, 1.19	6.52, 0.54	5.53, 1.39
	10.09, 0.85	7.10, 0.57	3.46, 3.24
	10.04, 0.95	6.98, 0.66	5.56, 0.78
	8.67, 2.61	4.90, 2.31	5.01, 1.60
	9.13, 1.69	4.92, 1.65	5.57, 1.52
	9.25, 1.91	5.31, 1.87	5.76, 1.67
C	9.24, 0.81	4.62, 0.67	5.43, 0.59
	9.89, 0.53	4.90, 0.73	5.43, 0.59
	10.04, 0.61	4.88, 0.69	5.55, 0.57
	9.51, 2.76	4.61, 1.69	5.24, 1.90
	9.19, 2.25	5.10, 1.71	5.49, 2.31
	9.32, 1.91	5.08, 1.41	5.11, 1.43
D	10.34, 0.60	7.60, 1.02	6.42, 0.54
	10.66, 0.81	6.13, 0.50	6.16, 0.63
	9.62, 0.63	7.26, 0.52	6.44, 0.71
	10.97, 2.36	6.05, 1.34	6.90, 1.20
	10.91, 2.27	6.04, 1.36	7.25, 1.12
	10.56, 1.80	6.07, 1.09	6.49, 1.41

[1] Table doublet entries = amount retained after application, amount retained after partial removal.

[2] The first three replicates for each subject and oil are from experiment three measurements; the last three replicates are from experiment two measurements.

APPENDIX F

ANOVA Tables: Amount of Liquid Retained on the Surface of Hands, Wipe and Immersion Tests

Table F-1. ANOVA Statistics for Amount of Liquid Retained on the Surface of Hands after Application, Wipe Tests

Factor	Degrees of freedom DF	Sum squares SS	Mean square MS=SS/DF	Variance ratio F=MS/MSE[8]	Significance probability
Subject, S[1]	3	7.485	2.495	23.42	>0.99
Liquid, L[2]	2	6.443	3.221	30.23	>0.99
Test, T[3]	1	1.133	1.133	10.63	>0.99
S x L[4]	6	4.864	0.811	7.61	>0.99
S x T[5]	3	0.367	0.122	1.15	
L x T[6]	2	0.247	0.124	1.16	
S x L x T[7]	6	0.080	0.013	0.12	
Error	72	7.671	0.106	1.00	

[1] Subject factor levels = A, B, C, D.
[2] Liquid factor levels = mineral oil, cooking oil, bath oil.
[3] Test factor levels = initial wipe test, secondary wipe test.
[4] Subject-Liquid interaction.
[5] Subject-Test (Application/Removal) interaction.
[6] Liquid-Test interaction.
[7] Subject-Liquid-Test interaction.
[8] Larger variance ratios indicate larger mean squares (variances) caused by specific factors relative to the common error mean square, MSE, caused by random variations. Thus, the larger the variance ratio, the larger is the variability due to specific factors relative to the variability due to common random factors, and so the more significant (a source of variability) is the factor with which the ratio is associated.

Table F-2. ANOVA Statistics for Amount of Liquid Retained on the Surface of Hands after Partial Removal, Wipe Tests

Factor	Degrees of freedom DF	Sum squares SS	Mean square MS=SS/DF	Variance ratio F=MS/MSE[8]	Significance probability
Subject, S[1]	3	1.665	0.555	22.44	>0.99
Liquid, L[2]	2	0.452	0.226	9.14	>0.99
Test, T[3]	1	0.652	0.652	26.35	>0.99
S x L[4]	6	0.377	0.063	2.54	>0.95
S x T[5]	3	0.377	0.112	4.54	>0.99
L x T[6]	2	0.121	0.061	2.44	
S x L x T[7]	6	0.029	0.005	0.19	
Error	72	1.781	0.025	1.00	

[1] Subject factor levels = A, B, C, D.
[2] Liquid factor levels = mineral oil, cooking oil, bath oil.
[3] Test factor levels = initial wipe test, secondary wipe test.
[4] Subject-Liquid interaction.
[5] Subject-Test (Application/Removal) interaction.
[6] Liquid-Test interaction.
[7] Subject-Liquid-Test interaction
[8] Larger variance ratios indicate larger mean squares (variances) caused by specific factors relative to the common error mean square, MSE, caused by random variations. Thus, the larger the variance ratio, the larger is the variability due to specific factors relative to the variability due to common random factors, and so the more significant (a source of variability) is the factor with which the ratio is associated.

Table F-3. ANOVA Statistics for Amount of Liquid Retained on the Surface of Hands after Full Removal, Wipe Tests

Factor	Degrees of freedom DF	Sum squares SS	Mean square MS=SS/DF	Variance ratio F=MS/MSE[8]	Significance probability
Subject, S[1]	3	0.829	0.276	9.67	>0.99
Liquid, L[2]	2	0.076	0.038	1.33	
Test, T[3]	1	0.807	0.807	28.24	>0.99
S x L[4]	6	0.454	0.076	2.65	>0.95
S x T[5]	3	0.544	0.181	6.35	>0.99
L x T[6]	2	0.100	0.050	1.75	
S x L x T[7]	6	0.103	0.017	0.60	
Error	72	2.057	0.029	1.00	

[1] Subject factor levels = A, B, C, D.
[2] Liquid factor levels = mineral oil, cooking oil, bath oil.
[3] Test factor levels = initial wipe test, secondary wipe test.
[4] Subject-Liquid interaction.
[5] Subject-Test (Application/Removal) interaction.
[6] Liquid-Test interaction.
[7] Subject-Liquid-Test interaction
[8] Larger variance ratios indicate larger mean squares (variances) caused by specific factors relative to the common error mean square, MSE, caused by random variations. Thus, the larger the variance ratio, the larger is the variability due to specific factors relative to the variability due to common random factors, and so the more significant (a source of variability) is the factor with which the ratio is associated.

Table F-4. ANOVA Statistics for Amount of Liquid Retained on the Surface of Hands after Application, Immersion Test

Factor	Degrees of freedom DF	Sum squares SS	Mean square MS=SS/DF	Variance ratio F=MS/MSE[4]	Significance probability
Subject, S[1]	3	40.11	13.37	48.60	>0.99
Liquid, L[2]	2	303.98	151.99	552.90	>0.99
S x L[3]	6	7.59	1.27	4.60	>0.99
Error	60	16.49	0.27	1.00	

[1] Subject factor levels = A, B, C, D.
[2] Liquid factor levels = mineral oil, cooking oil, bath oil.
[3] Subject-Liquid interaction.
[4] Larger variance ratios indicate larger mean squares (variances) caused by specific factors relative to the common error mean square, MSE, caused by random variations. Thus, the larger the variance ratio, the larger is the variability due to specific factors relative to the variability due to common random factors, and so the more significant (a source of variability) is the factor with which the ratio is associated.

Table F-5. ANOVA Statistics for Amount of Liquid Retained on the Surface of Hands after Partial Removal, Immersion Test

Factor	Degrees of freedom DF	Sum squares SS	Mean square MS=SS/DF	Variance ratio F=MS/MSE[4]	Significance probability
Subject, S[1]	3	8.07	2.69	14.97	>0.99
Liquid, L[2]	2	2.79	1.39	7.76	>0.99
S x L[3]	6	2.62	0.44	2.43	>0.95
Error	60	10.78	0.18	1.00	

[1] Subject factor levels = A, B, C, D.
[2] Liquid factor levels = mineral oil, cooking oil, bath oil.
[3] Subject-Liquid interaction.
[4] Larger variance ratios indicate larger mean squares (variances) caused by specific factors relative to the common error mean square, MSE, caused by random variations. Thus, the larger the variance ratio, the larger is the variability due to specific factors relative to the variability due to common random factors, and so the more significant (a source of variability) is the factor with which the ratio is associated.