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Batch Lot Variability in Permeation Through Nitrile Gloves

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Many factors should be considered in the selection of chemical protective clothing, but the majority of selections are based on manufacturers' permeation data composed of average results for three replicates; usually no information about variability is provided. It was hypothesized that variability across batch lots might be considerable, and that variability may be due to cure factors that may vary from one site to another within the same company. Glass transition temperature (T_g) has been demonstrated to be an indicator of cure, and so its relationship to permeation parameters was examined. Steady state permeation rate, breakthrough detection time (BDT), cumulative permeation at 125 minutes (ASTM F1407), and T_g (ASTM E1356) were measured for two makes of nitrile gloves presumably in four batches. T_g was not related to any of the permeation parameters even though batch-to-batch variability was statistically significant for all parameters except BDT. A comparison with recent ASTM round-robin results indicates that some of the variability may be due to the method; however, manufacturer quality control must be suspected as the major source of variability based on the results of this study.

Keywords: chemical protective clothing, nitrile, permeation, variability

Since the late 1970s and the formation of ASTM Committee F-23 and the subsequent publication of the standard permeation test method, F739,[1] a tremendous amount of permeation data has been published and interest in dermal exposure has been heightened.[2–5] There are several sources for polymer permeation information available (see, for example, references 6 and 7). In addition, generally manufacturers provide permeation charts to use for the selection of protective clothing. Typically, as per ASTM method,[1] the reported data should include normalized breakthrough time (but often include instead breakthrough detection time, BDT) and steady state permeation rate (SSPR). These data are usually reported as single values that, in fact, are the average of three replicates as required in the ASTM method. However, very seldom is the variability in the three replicates reported. Thus, the user is likely to make a decision based on a single average value reported in the literature.

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There are many factors that should go into the selection of protective clothing that are not reflected in the average steady state permeation rate or breakthrough time values. These would include cost, acceptability to worker, heat stress, dexterity, tactility, tear and cut resistance, and a host of other factors.[8,9] These are often difficult to consider as they have not been quantitatively characterized.

Thus, if a hygienist had to make a decision between one material having an SSPR of 20 units and another having an SSPR of 40 units, the obvious choice is the protective clothing having the lower steady-state rate, all other things being equal. However, if the hygienist knew the variability in the three replicates that went into the above averages—for example, 2, 2, and 56 for the first and 39, 40, and 41 for the second—then he or she might be more likely to pick the second material. The purpose of this study was to characterize the variability across batch lots for two manufacturers of butadiene-acrylonitrile copolymer (nitrile) gloves. Nitrile was chosen because of its extensive use in industry as determined by questioning a major safety supply company.

METHOD AND MATERIALS

Materials

Unlined, unsupported nitrile gloves were obtained from several suppliers. The manufacturers of the gloves were Ansell-Edmont (Sol-Vex®, 37-155, 15 mil or 0.038 cm) and MAPA, formerly Pioneer (Stansolv, A15, 15 mil or 0.038 cm). The Edmont gloves were obtained from different suppliers. Two batches of the MAPA gloves were obtained from the manufacturer, and it was clear that they were from different production runs because MAPA complied with a request to provide the manufacturing location and date of these gloves. The other two batches were obtained from suppliers. For each manufacturer it was assumed that four batches were obtained from different production runs, since the gloves from suppliers came from different parts of the country and were obtained at different times. From each batch, five gloves were sampled and the permeation parameters measured. All glove samples were taken from the back of the hand.

In all tests reagent grade 2-ethoxyethanol acetate was used as the permeant. It was selected because in preliminary tests little swelling of the polymer was observed, and a reasonable breakthrough time (less than 120 minutes was the original criterion) was observed. Ethyl acetate, 2-ethoxyethanol, 1,1,1-trichloroethane, and carbon disulfide were also tried, but were found unacceptable due to their swelling of the polymer.

Method

For this project ASTM method 1407-92[10] was used. This permeation method uses a gravimetric analytical procedure. An open aluminum test cell is used, across which the polymer is placed after the cell has been filled with the permeant. The cell is then inverted to expose the polymer to the liquid, and the cell is weighed. The weight may be recorded continuously if the balance has the appropriate output. Alternatively, the cell may be weighed at periodic intervals. The weight is plotted versus time to reduce the data to the permeation parameters of SSPR and BDT.

A few modifications to the method were made. Unlike the method that simply calls for the test to be run at room temperature, the test environment was carefully controlled. An environmental chamber was made from an inverted Styrofoam™ ice chest (approximately 1 cubic foot or 30 cm on a side). A hinged door was added to access the test cell. A 250-watt light bulb (needed to overcome cooling caused by airflow) served as a heat source, and a fan was used to circulate the air within the chamber. The light source was thermostatically controlled, and the temperature monitor was placed slightly to the side, and level with the top, of the permeation cell. It was checked regularly for accuracy with a calibrated thermometer, traceable to the National Institute for Standards and Technology.

The cell was modified by replacing three of the six retaining ring screws with 1-inch (2.5 cm) long screws to provide a clearance space beneath the cell. This allowed air movement beneath the cell, which was provided by the fan and also by the laboratory hood in which the environmental chamber was placed. The environmental chamber was raised ½-inch above the hood floor, and airflow at this opening was measured at 600–650 ft/min. It is roughly estimated, based on the size of the opening that faced the hood sash and the air velocity, that 40 air changes per minute would have occurred. This should have provided adequate ventilation of the chamber so as not to allow buildup of the evaporated permeant, which would have impeded permeation. The temperature was monitored regularly and kept at 25–26°C.

The permeation cell was removed from the chamber and weighed in its inverted position at varying intervals depending on the stage of the test. At early times (first 30 minutes), weighing was every 1 minute so as to detect breakthrough, then at 5-minute intervals. The cell was removed by lifting the hinged door and removing the cell with tongs. The cell was then placed on the balance, weighed, and returned to the test chamber. The weighing procedure was done rapidly (<10 sec), and some cooling would have occurred. The effect of this cooling would be to increase the BDT, but the effect should have been small and consistent from test to test. Because the ambient temperature was approximately 21°C, only a small temperature gradient would have existed.

Analytical

A Mettler top-loading balance, model number BB240, with a capacity of 240 g and readability and reproducibility of 0.001 g, was used. The balance was shielded on five sides by cardboard to reduce the effects of air currents on repeatability and limit of detection.

To determine the limit of detection of the balance, two blank permeation test runs were made using an empty cell placed in the environmental chamber. The cell was removed from the chamber and weighed every minute for a total period of 30 minutes. The standard deviation was determined for each run, and the two standard deviations were pooled. The limit of detection was defined as three times this pooled standard deviation, or 0.002 grams.

Data Reduction

Breakthrough detection time was defined as that weighing time just prior to when the weight loss first exceeded the LOD. In addition, weight loss had to continue thereafter in a monotonic fashion. The BDT was determined by graphically analyzing the data.

The steady-state permeation rate was determined by graphing the results as weight versus time. The last four to eight consecutive points were chosen for linear regression to obtain a maximum correlation coefficient. From this regression line a slope (weight lost per time) was found and the SSPR calculated by dividing the slope by the exposed area of the specimen (47.8 cm^2). From the first few tests, which were run for about 180 min, it was deduced that to achieve a correlation coefficient for weight versus time of 0.98 or greater, the test needed to be run for at least 125 minutes.

In addition, the cumulative permeation at 125 minutes was determined for each sample. Since the calculation of steady-state rate depends on the points selected in the regression analysis, the number of points selected, and the correlation coefficient, it was thought that cumulative permeation mass might be less subject to error. This is also an option in F1407.

Glass Transition Temperatures

Glass transition temperature (T_g) is the temperature below which local molecular motion of the polymer molecules virtually stops.[11] Above this temperature the polymer is more plastic, while below it the polymer is glass-like. T_g is affected by the degree of bonding or electrostatic interactions between polymer chains. In this study T_g was determined using differential scanning calorimetry and ASTM method E1356-91.[12]

Hypotheses

The hypotheses tested were that for each manufacturer there were significant batch lot mean differences and that between manufacturers there were significant mean differences in the permeation test parameters. These hypotheses were tested using a one-way analysis of variance (ANOVA). Additionally, tests for equality

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of variances (Bartlett's test) were performed to verify the assumption underlying the ANOVA that variances of the sample populations are equal. Bartlett's test compares the weighted arithmetic average of the sample variances with their weighted geometric average.

It was also hypothesized that T_g would vary with permeation parameters. It has been shown to be a function of cure properties, i.e., the time, temperature, and amount of crosslinking agent used in the curing process. Cured elastomers have higher T_g than uncured elastomers.[13] Thus, if batch lot permeation differences were found and correlation could be found between T_g and the permeation properties, then it could be assumed that curing procedural differences are important. Of course, this assumes that even more basic quality control issues are well-controlled by the manufacturer. For example, if the copolymer ratio were not well-controlled, then this would affect permeation properties and T_g in unpredictable ways. It was suspected that cure time and temperature could be most easily manipulated, even by individual production workers, and that weather and production pressures might cause these factors to be most easily varied.

RESULTS

The results are visually summarized in Figures 1, 2, and 3, which seem to indicate that there is no difference between batch lot means, both within and between the two manufacturers for the permeation parameters. However, the analysis of variance did indicate that the means of cumulative permeation mass (CP) and SSPR for both manufacturers were significantly different within and between manufacturer, while breakthrough detection time batch means were not (see Table I).

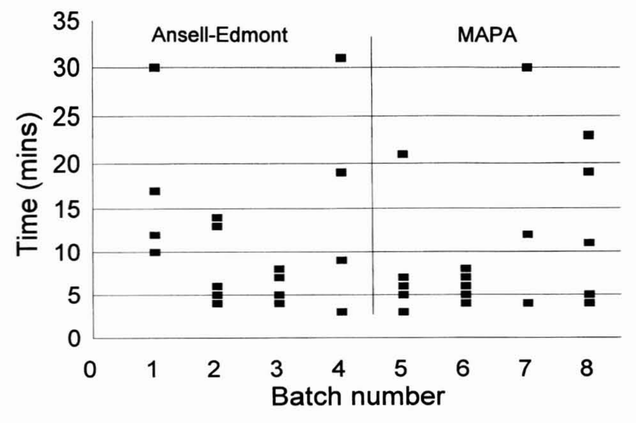

FIGURE 1. Breakthrough detection times for each of five replicates per batch

Table I shows significant differences in some of the batch variances. This constitutes a violation of one of the assumptions of the ANOVA. The effect of this violation is to make it more difficult to fail to reject the null hypothesis. In other words, we would more likely conclude no difference when there is one. For the SSPR and CP data (for which the batch variances are significantly different), this violation is not important since the null hypothesis that the batch means are equal is rejected anyway. However, for the BDT results it is important since the hypothesis for the means was not rejected. A logarithmic transformation of these data failed to improve the variance inequality.

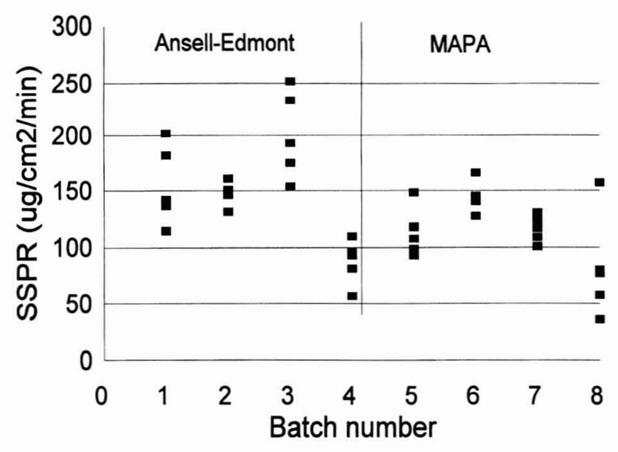

FIGURE 2. Steady-state permeation rates for each of five replicates per batch

Table I shows the glass transition temperature data. These vary significantly from batch to batch for the Ansell-Edmont gloves,

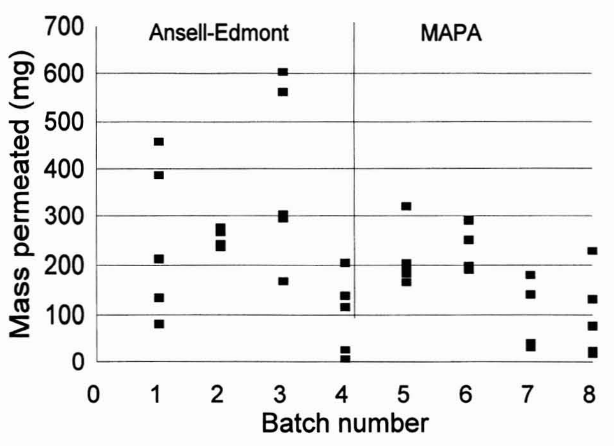

FIGURE 3. Cumulative permeation at 125 minutes for each of five replicates per batch

but the batch-to-batch differences were not quite significant ($p = 0.06$) for the MAPA gloves.

TABLE I. Batch Mean and Variance Comparisons by Manufacturer[A]

Producer	Factor	Means Comparison (p-value)	Variance Comparison (p-value)
Ansell	CP	0.026[A]	0.003[B]
MAPA	CP	0.003[A]	0.73
Ansell	BDT	0.17	0.017[B]
MAPA	BDT	0.61	0.02[B]
Ansell	SSPR	0.0001[A]	0.1
MAPA	SSPR	0.017[A]	0.04[B]
Ansell	T_g	0.01[A]	0.19
MAPA	T_g	0.06	0.24

[A]Statistically significant differences between the batch means at the 95% level, as determined by one-way ANOVA
[B]Statistically significant differences between the batch variances at the 95% level, as determined by Bartlett's test

DISCUSSION

It may be postulated that factors introduced by the manufacturing process may account for lot-to-lot variability. For example, variability in the recipe from one manufacturing site or from one time of year to another could be important. This would include the amount of plasticizer used; the way that vulcanization, cure, or crosslinking[14] is attained, and the amount of crosslinking agent that is used to attain it; the cure time and temperature; and in the case of nitrile rubber, the ratio of the two principal copolymers used, acrylonitrile and butadiene.

It was postulated that cure time and temperature could vary most easily from one site to another and that this may be reflected in the T_g. Thus, there should be a correlation between T_g and the permeation parameters. However, correlation studies of these parameters indicated that there was no relationship between T_g and any of the three permeation parameters. In all cases the coefficients of determination were less than about 10%. From these results it is difficult to draw any conclusions. It may be that T_g is not the parameter that best indicates cure time or temperature, or it may be that cure time and temperature are reflected in T_g but that cure time and temperature are not the variables affecting permeation variability in this case.

On the other hand, it is obvious that there is significant variability in permeation parameters both within and between batches. Unfortunately, from this study one can only hypothesize on the possible causes of the variability. Plasticizers are often used in nitrile compounds to allow for low temperature flexibility. Typically nitrile latexes for gloves range from a 26 to 39% acrylonitrile content.[15] Variability in the amount of plasticizers and monomers would certainly lead to permeation variability. Variability caused by the test method is another possibility.

ASTM Round-Robin Comparison

While the gravimetric ASTM method (F1407) has not been the subject of an extensive round-robin test by ASTM, the chemical assay method (F739), which usually employs gas chromatographic detection, has been the recent subject of extensive round-robin tests.[1] In that round-robin test, three samples (FEP Teflon®, butyl rubber, and neoprene rubber) were taken from sheets of those materials and distributed to seven laboratories. Each laboratory ran the F739 method. It would be expected that little variability between polymer specimens would be attributable to the polymer sheet itself. Indeed, the specimens from the butyl were distributed systematically, and there was no difference among those samples taken from the middle of the sheet and those from the sides of the sheet (author's own analysis). Thus, the variability found in this round-robin should be indicative of the variability in the method itself and not so much of the variability in the polymer specimens.

For the purpose of this comparison, assume that the variability in method F739 is similar to that of F1407. Admittedly, this may not be the case. The F739 method may be more variable because it is more complicated. While gravimetric analyses are inherently more precise than other instrumental methods, there are portions of the F1407 method, such as the need to handle the test cell for weighing, that would contribute additional variability.

Tables II and III show the coefficients of variation for the data in this study. Table IV shows the average within-laboratory coefficient of variation (CV_W) and the average between-laboratory coefficient of variation (CV_B) for the round-robin. Standard deviations (S_W and S_B) are also shown. Of most use here is the within-average coefficient of variation presented in the ASTM round-robin since this represents the performance of an average laboratory.

It might be expected that the authors' laboratory would have performed as well or better than the ASTM round-robin laboratories, since in this study the temperature was the same for every test.

TABLE II. Ansell-Edmont Batch Lot (n=5) Statistics

Factor	Batch #	Mean	SD^A	CV^B
BDT (min)	1	15.8	8.4	0.53
	2	8.4	4.7	0.56
	3	6.2	1.6	0.26
	4	14.2	11.0	0.78
				0.53^C
SSPR (µg/cm²/min)	1	155	36	0.23
	2	147	11	0.07
	3	202	41	0.20
	4	87	20	0.23
				0.57^C
CP (mg)	1	255	162	0.63
	2	259	18	0.07
	3	386	188	0.49
	4	99	82	0.82
				0.19^C
T_g (°C)	1	−3.85	1.71	0.44
	2	−4.77	0.28	0.06
	3	−6.34	1.28	0.20
	4	−7.66	0.63	0.08
				0.25^C

^A SD=standard deviation
^B CV=coefficient of variation (SD/mean)
^C CV=pooled CV

TABLE III. MAPA Batch Lot Statistics

Factor	Batch #	Mean	SD^A	CV^B
BDT (min)	5	8.4	7.2	0.86
	6	6.0	1.6	0.26
	7	10.4	11.3	1.08
	8	12.4	8.4	0.68
				0.72^C
SSPR (µg/cm²/min)	5	113	22	0.19
	6	144	14	0.10
	7	116	12	0.10
	8	82	46	0.56
				0.30^C
CP (mg)	5	213	62	0.29
	6	244	48	0.20
	7	108	65	0.60
	8	97	87	0.90
				0.57^C
T_g (°C)	5	−6.53	0.16	0.02
	6	−6.71	1.0	0.15
	7	−5.56	0.53	0.1
	8	−7.25	0.58	0.08
				0.09^C

^A SD=standard deviation
^B CV=coefficient of variation (SD/mean)
^C CV=pooled CV

TABLE IV. F739 Round-Robin Results for Seven Laboratories

Material	Average	S_W	S_B	CV_W	CV_B
Steady-state permeation rate (μg/cm²/min) statistics					
FEP	0.06	0.013	0.04	0.21	0.70
Butyl	0.38	0.17	0.2	0.46	0.53
Neoprene	245	54	54	0.22	0.22
Normalized breakthrough time (min) statistics					
FEP	A				
Butyl	198	56	96	0.28	0.48
Neoprene	7.2	0.83	1.85	0.12	0.26

[A]Normalized breakthrough times for FEP are not reported because permeation rates did not reach 0.1 mg/cm²/min.

In addition, consistent protocols were used to determine SSPR and BDT. For SSPR the pooled coefficients of variation were 0.19 and 0.30 in this study, similar to the round-robin values of 0.21 to 0.46. Thus, for SSPR it would appear that nitrile from different batches is little or no more variable than the three round-robin polymers taken from the same sheet. However, temperature varied in the round-robin, but did not in this study. Thus, the CVs for this study should have been less.

For BDT, the CVs from the round-robin were 0.12 and 0.28, whereas in this study the pooled values were 0.53 and 0.72. (It should be noted that in the round-robin a normalized breakthrough time was used, i.e., the time to a steady-state rate of 1 μg/cm²/min.) Again, less variation in the results of this study would be expected, but the opposite was the case.

Importance of the Variability

The important effect of variability, regardless of its source, is on the user. When the user selects a particular glove, what does the reported breakthrough time and steady-state rate actually mean relative to the individual glove being used by the worker? Ansell-Edmont appears to recognize this variability, at least in the SSPR value. They report that their style no. 37-165 (a 22-mil, 0.056-cm, supported nitrile glove) has a permeation rate of 9 to 90 μg/cm²/min[16] when exposed to 2-ethoxyethanol acetate. (Ansell-Edmont does not report data for the 15-mil gloves used in this study. It is not known if the polymer recipe for this 22-mil glove is different than that of the 15-mil glove used here, but both are called Sol-Vex.) This permeation rate multiplied by the film thickness yields a permeability constant of 0.5 to 5 μg/cm/min. In this study, permeability constants for Ansell-Edmont's 15-mil gloves ranged from roughly 1.9 to 9.5 μg/cm/min, approximately in agreement with Ansell-Edmont's data for this polymer. Thus, they correctly report about an order of magnitude of uncertainty in SSPR.

A similar uncertainty exists for BDT data. From the current study, the 2.5 and 97.5 percentiles on breakthrough detection time are 0 to 24 minutes for the MAPA data with a mean of 9 minutes, and 0 to 23 minutes for the Ansell-Edmont data with a mean of 11.5 minutes. This would indicate that these 15-mil gloves should not be used in continuous exposure situations. However, Ansell-Edmont's 22-mil, supported version of the nitrile glove has a reported average breakthrough detection time of 90 minutes.[16] This would seem a bit high, but moreover, it would seem that a reported range for BDT would be appropriate as for SSPR. It should be noted that apparently only Ansell-Edmont, among the manufacturers, reports a range for any data.

Explaining the Method Variability

There are several reasons that the ASTM methods may give considerably variable results across replicates and laboratories. Temperature has been mentioned. However, the determination of SSPR and breakthrough are subject to subjective error. For SSPR, use of slightly differing time intervals from the permeation curve to determine the slope for the SSPR calculation can make a considerable difference. For example, Figure 4 shows the actual permeation curve from this study for Batch 3, Sample B from Ansell-Edmont. If the region chosen to calculate the steady-state permeation rate had been from 85 to 105 minutes, then the steady-state permeation rate would have been 100 μg/cm²/min with a determination coefficient of 0.998. If the region used were from 85 to 125, the rate would be 145, with $r^2 = 0.97$. Actually, the last 5 points from 105 to 125 minutes were used to yield a rate of 193 μg/cm²/min with a determination coefficient of 0.997. Thus, both the number of points and location or timing is important. In this study several runs of up to 180 minutes were necessary to determine a reliable time that all runs could be ended.

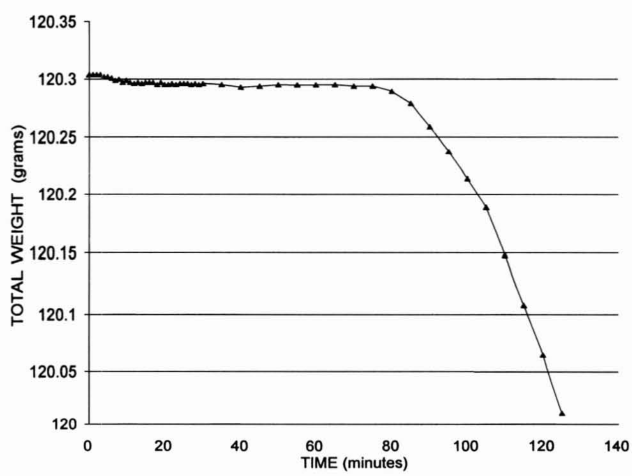

FIGURE 4. Weight of the test cell apparatus, polymer, and permeant versus time for Ansell-Edmont Batch 3, Sample B

There are many ways to examine permeation data graphically, and in many cases these can be misleading. Without the use of statistics to maximize the correlation coefficient in the regression analysis, one may be led to conclude that steady-state rate has been reached when in fact it has not. Standardization of the determination of SSPR would seem a good way to improve both ASTM permeation methods.

CONCLUSIONS

The results indicate that there was considerable batch lot and intermanufacturer variability. The variability in the ASTM method may account for some of this, but temperature was the same in each test, and the determination of SSPR and BDT were standardized to reduce these effects. Thus, the variability is likely to be related also to quality control. T_g had no relationship to the permeation parameters. Thus, the batch lot variability is probably related to factors other than or in addition to cure time and temperature.

The trust that one may place in published permeation data is likely no different than the trust that one should place in a published threshold limit value of the American Conference of

Governmental Industrial Hygienists[17] or the protection factor one may obtain in a respirator quantitative fit test. In other words, these values should be used as guidelines only. In the case of gloves or protective clothing, the published value should be used as a relative measure for selecting one glove over another. Even so, errors may occur so that such a selection may be incorrect. Thus, it is important that the industrial hygienist train workers adequately to recognize possible symptoms of exposure to the skin, and that where possible, industrial hygienists conduct field studies of the adequacy of protective clothing to indicate the exposure of the skin during actual use conditions. For nonvolatile chemicals, this may be done by placing some type of absorbent under the protective clothing and then extracting the permeant from the absorbent.[18,19] In addition, charcoal cloth has been used to monitor volatile compounds, such as heptane, under chemical protective gloves.[20]

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