Double gloving of disposable nitrile gloves exposed to diethylene glycol mono-n-butyl ether

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Abstract

Double gloving of disposable gloves is now commonplace in healthcare settings when extra protection is needed against aqueous solutions and especially for antineoplastic drugs in isotonic aqueous media. In the present study, an ASTM F739 2.54 cm cell with closed-loop water collection without recirculation at 35 °C in a moving tray water bath was used to test the permeation of diethylene glycol mono-n-butyl ether (DGBE) through four types of disposable nitrile gloves that were singly and doubly layered in the permeation cell. Samples were taken over 8 hr for capillary gas chromatograph-mass spectrometer quantitation. The breakthrough time (t_n) at a permeation of 250 ng/cm^2 increased as thickness increased for single layers, but the steady-state permeation rates P_s in μg/cm^2/min did not always decrease with increasing thickness. The double-layer t_n, P_s and thickness were also more variable relative to a single layer. The thinnest glove with 80 μm thickness showed a $t_n = 0$–5 min whereas its double layer was 15–20 min. The thickest glove of 132 μm exhibited a $t_n = 10$–15 min but its double layer was $t_n = 45$–55 min. The adjusted double-layer average t_n divided by the adjusted single-layer average t_n was 4.0 ± 0.8. The adjusted average single-layer P_s divided by the adjusted average double-layer P_s was 3.5 ± 0.8. Other results showed that the average glove swelling was <10%; microscopic and leak testing indicated no penetration and reflectance infrared analysis also showed no chemical changes on the inside glove surfaces. Thus, the permeations were adjudged to obey Fick's First Law of Diffusion to allow calculation of diffusion coefficients D in cm^2/min. The average single-layer D divided by the average double-layer D was 1.3 ± 0.2. Double gloving in the field is therefore also probably more protective than single gloving against DGBE for the four types of disposable nitrile gloves tested.

Keywords

Breakthrough time; diethylene glycol mono-n-butyl ether; disposable nitrile gloves; double gloving; permeation

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Introduction

In 2017, there were 24,800 illnesses recorded across all industries in the United States as a result of skin exposure, some 15% of all cases and about 1.7 times those for inhalation exposures (Bureau of Labor and Statistics 2017). Many exposures occurred with semi-/non-volatile organic chemicals.

Chemically resistant gloves should be worn for optimum personal protection against chemicals. Often disposable gloves may be the only ones available. To assess how well gloves perform as barriers, permeation (mass transfer at the molecular level) and penetration (mass transfer through nano- and micro-holes and seams) tests are performed. Limited permeation data exist for semi-volatile organic chemicals for disposable gloves, the present study helping to remedy this situation

Permeation standards

Most researchers and glove companies in the United States have used the open-loop mode with gas collection of the ASTM F739-99 (American Society of Testing and Materials (ASTM) 1999) and ASTM F739-12 (American Society of Testing and Materials (ASTM) 2012) methods to generate permeation data from circular glove pieces for organic solvents at user-specified temperatures within ± 1 °C (American Society of Testing and Materials (ASTM) 1999) or at 27 ± 1 °C (American Society of Testing and Materials (ASTM) 2012). The major permeation parameters are the steady-state permeation rate (P_s), the normalized breakthrough time (t_n), and the standardized breakthrough time (t_s). In ASTM F739-99, the t_n was the time at which the permeated mass/area reached 250 ng/cm^2 for a closed-loop system or the permeation rate of 100 ng/cm^2/min was reached for an open-loop system. In ASTM F739-12, t_s is defined at 100 ng/cm^2/min for both open- and closed-loop systems at 27 ± 1 °C.

Compounds with low vapor pressure may not volatilize completely at the collection side surface in gas collection systems (Schwope et al. 1988). If the chemical does not volatilize completely, then t_n or t_s may not be accurate. Methods that use liquid collection are valid alternatives provided the permeant is solubilized, the solvent does not degrade or back-permeate the glove material, and the collection side is mixed. Water is the preferred collection solvent.

ASTM D6978-05 tests pieces of disposable medical gloves in the large ASTM-F739 permeation cell exposed to aqueous solutions of specific chemotherapy agents at their highest use concentrations over 4 hr sampled at 30-min intervals from an aqueous closed-loop collection system without recirculation (American Society of Testing and Materials (ASTM) 2013). The ASTM D6978-05 permeation method differs from ASTM F739 in that permeations are at 35 °C, a permeation rate of 10 ng/cm^2/min defines the breakthrough detection time (decreased from the ASTM F739 analogous t_s at 100 ng/cm^2/min due to antineoplastic agent toxicity); the thinnest portion of the glove from either the cuff or the palm is evaluated rather than the palm or top of the palm for ASTM F739. The standard was reapproved in 2013. ASTM D6978-05 has a realistic temperature for a tightly worn glove, being at skin surface temperature (Nadel et al. 1971), whereas ASTM F739-12 recommends

27 °C, and previous versions of ASTM F739 recommended no temperature at all. Similar types of permeation cells and procedures are mandated for glove permeation testing within the European Community through the EN 374-3 and ISO 6529 methods with their t_n at 1,000 and 100 ng/cm^2/min being analogous to t_s (Chao et al. 2007).

Double gloving

Double gloving as a method to protect personnel has been largely practiced in the healthcare worker community with most of the previous studies being done in Europe. Thus, the permeation of 70% isopropyl alcohol through disposable natural rubber glove pieces using an EN 374-3 permeation cell showed that the 4.6 min breakthrough time (BT) at 1,000 ng/cm^2/min at 23 °C of the single 0.022 cm glove piece increased to 80 min or 17 times longer upon double layering (Maekelae et al. 2003a). Formalin solutions permeated a single natural rubber disposable glove piece (BT of 17–67 min at 100 ng/cm^2/min at 23 °C) but did not permeate double layers (Maekelae et al. 2003b). The BT of 25% tetramethyl ammonium hydroxide at 250 ng/cm^2/min in water through double natural rubber glove pieces at 23 °C was 17 times longer than for a single glove, with a P_s 3.6 times lower (Su et al. 2013). The BT of the natural rubber outside/nitrile inside combination was 1.35 times longer than when the order of glove layers was reversed. Thus, the more resistant glove should be on the inside when donning dissimilar gloves.

Carmustine in aqueous solution used in chemotherapy was found to permeate a single-layer natural rubber latex glove after 180 min with detection BT at about 45 min in an EN 374-3 permeation cell with water as collection solvent at 20 °C but permeation rate did not reach 1.0 μg/cm^2/min (Klein et al. 2003). Double layered latex did not allow carmustine permeation. Seventeen antineoplastic drug solutions were evaluated under conditions of dynamic contact at 37 °C, and with and without pretreatment with 70% isopropyl alcohol or ethanol. None of the permeation rates exceeded 100 ng/cm^2/min but carmustine exposure at 60 min exceeded 10 ng/cm^2/min at 35 °C for two single natural rubber gloves. Double gloving resulted in no observed permeation in all instances even at 43 °C (Capron et al. 2012). Five antineoplastic agents (cyclophosphamide, doxorubicin hydrochloride, etoposide, fluorouracil, and paclitaxel) were evaluated at their maximum administration concentrations against three disposable glove types (chlorinated latex, non-chlorinated latex, and nitrile of different thicknesses) within a continuous flow in-line permeation cell (Oriyama et al. 2017). Only cyclophosphamide and fluorouracil permeated through latex, the chlorinated glove type being more resistant. No antineoplastic agents permeated nitrile gloves. Double layering with chlorinated latex resisted more than single gloving. A mixture of 50:50 2-hydroxyethyl methacrylate (HEMA) and triethylene glycol dimethacrylate (TEGDMA) used in dentistry to challenge natural rubber and PVC disposable gloves resulted in breakthrough for both within ten min in an EN 374 permeation cell (Maekelae et al. 1999). Natural rubber was more resistant, and double layering of natural rubber with polyethylene gloves lengthened BTs to over 480 min. Based on the layering results with European permeation cells, ASTM cells are expected to produce quality data in similar investigations.

Industrial workplace double gloving

Most previous double gloving studies have involved aqueous challenge and collection solutions with disposable gloves in closed-loop collection systems without recirculation. Disposable gloves are designed to resist water. The European studies (Maekelae et al. 1999, 2003a, 2003b; Klein et al. 2003; Capron et al. 2012) used double layering of circular glove pieces in their permeation cells as a surrogate for field double gloving.

There are no literature reports of such double gloving simulations for pure organic solvents. Suitable test compounds must not degrade the glove (American Society of Testing and Materials (ASTM) 1999, 2012, 2013). Since disposable gloves are designed to resist water H-O-H, the closest organic molecule to water is an alcohol R-O-H where R is alkyl, alicyclyl, aryl, or other multifunctional non-polar entity.

Such a multifunctional alcohol is diethylene glycol mono-*n*-butyl ether (DGBE; n-butyl-O-CH_2CH_2-O-CH_2CH_2-OH; CAS RN 112-34-5). DGBE is water soluble, with a 230 °C boiling point and is used in brake fluids (the dominant use), paints and varnishes, household and healthcare facility soaps, cleaning liquids, detergents, pesticide formulation "inert components," brewing chemicals, textile processing, hair colorings, and cutting fluids (Hazardous Substance Data Bank 2020). The only occupational guideline is an 8-hr Threshold Limit Value (TLV®) of 10 ppm from the inhalable aerosol and vapor exposure associated with blood system, liver, and kidney effects (American Conference of Governmental Industrial Hygienists (ACGIH®) 2019). There is no "skin" notation. DGBE is a High Production Volume Chemical (over 1 million pounds imported and/or produced). The National Institute for Occupational Safety and Health (NIOSH) estimated 641,115 workers to have been potentially exposed in the United States in 1981–1983 (Hazardous Substance Data Bank 2020). The 2012 Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) Inventory Update Reporting Data from 16 reporting facilities ranged from 100–499 workers exposed per facility in non-confidential uses (Hazardous Substance Data Bank 2020). It is absorbed through the skin since its chief metabolite butoxyethoxyacetic acid was detected in worker urine after skin exposure. Allergic dermatitis after DGBE exposure was reported in a single case study in contradiction to animal study results. It is a mild skin irritant. Chemically protective gloves recommended as "very good" or "excellent" (indexed under butyl carbinol) for chemical resistance include nitrile, polyvinyl chloride, and supported polyvinyl alcohol (Ansell 2008) for consideration as material for disposable gloves for which there are no permeation data.

Thus, DGBE was chosen to be used in ASTM F739 permeation cells to compare its permeation of double layers of glove pieces simulating field double gloving, with its permeation through a single layer.

Methods

Glove selection

The four disposable nitrile glove types used were unlined, unsupported, powderless, and of unspecified thickness from Kimberly-Clark (Kimberly-Clark Professional 2013): Safeskin Blue (SB), Kimtech Blue (KB), Kimtech Purple (KP), and Kimtech Sterling (KS) (Fisher

Scientific, Pittsburgh, PA). The quality assurance and control measures employed by Kimberly-Clark for these nitrile gloves are known to be similar and minimizes interrun variation of the same type of glove if obtained from different manufacturers. Nitrile is one of the most used glove materials in healthcare activities (Azoth Analytics 2018), and is preferred to latex rubber because of allergy considerations. Kimberly-Clark also has an extensive permeation data base. However, there were no permeation data for DGBE, another reason to choose it for the present research in light of the CPC glove permeation data for DGBE (Ansell 2008).

Chemicals

DGBE, the challenge solvent, was of >99.5% purity from Fisher Scientific (Pittsburgh, PA). The 4-bromo-phenol internal standard (IS) for quantitation was obtained from Aldrich (St. Louis, MO). Sodium dichromate (99%) from Fisher Scientific was used for a saturated salt aqueous solution to generate a (55 ± 4) % relative humidity atmosphere for glove conditioning and reconditioning inside of a Pyrex glass vacuum desiccators from Fisher Scientific.

All water for aqueous solutions was from a Millipore Milli-Q Water System (Temecula, CA) and Millipore Simplicity Water Purification final polishing system (Temecula, CA). Helium (99.9999%) and nitrogen (99.9999%) were purchased from Air Liquide (El Segundo, CA).

Equipment

A Marathon digital micrometer from Fisher Scientific (Pittsburgh, PA) measured glove palm piece thickness at three random locations. Vernier calipers facilitated the measurement of glove piece diameters. Two sampling-side ASTM-type-I-PTC-600 permeation cells from Pesce Lab Sales (Kennett Square, PA) were used for permeation testing. A Fisher moving tray Model 127 Shaking Water Bath from Fisher Scientific (Pittsburgh, PA) allowed temperature control and mixing in the permeation cells that were immersed except for the top halves of their stems. The shaking water bath was modified with copper tubing bars to support clamps to hold the nearly immersed permeation cells in position. A torque wrench was used to tighten permeation cell nuts uniformly. A calibrated Fisher Scientific traceable printing hygrometer/thermometer was used for the measurement of relative humidity and temperature.

The GC-MS system used for analysis was an Agilent (Santa Clara, CA) 6890N Network GC with a 30 m $\times$ 0.25 mm HP-5ms chemically bonded (0.25-μm-thick film) fused silica capillary column in tandem with a quadrupole mass spectrometer, the Agilent 5973 Network Mass Selective Detector, operated at 70 eV electron impact energy at an ion source temperature of 230 °C. The GC-MS transfer line and GC injector temperatures were at 280 °C. Helium was the carrier gas at 3.0 mL/min.

Attenuated total reflectance-Fourier Transform infrared (ATR-FTIR) spectra were obtained on an Avatar 360 Fourier transform spectrometer system (ThermoNicolet, Madison, WI) that is a single-beam spectrophotometer using the reflectance mode and operated with OMNIC 6.0a software controlled by Windows 98 (Microsoft Corporation, Redmond, WA). The

crystal was diamond in the single-reflection horizontal attenuated total reflectance mode. The spectral range was 600–4,000 cm^{-1}. The number of scans was 128.

For the detection of micro-holes and -tears in glove materials a Frazier air permeability tester linked to a glove examination chamber (a 5-L polypropylene vacuum desiccator) and a computer controller were used (Mathews and Que Hee 2016). With glove pieces, the Frazier air permeability tester was set to 7–8" of H_2O vacuum pressure and water was added to the glove piece compartment and held for 90 sec to check for any leaks before and after permeation. Microscopic magnification of the glove surface was also used to determine whether micro holes or tears were present.

Procedures

GC-MS analysis—Aliquots injected for GC-MS were 2.0 μL in volume containing 2.4 μg/mL of IS. GC-MS quantitations were performed by the internal standard method whereby the area response of analyte injected divided by the area of the IS was interpolated on a linear plot of area of analyte standard divided by area of the IS versus mass of analyte injected. The linear portions of the plots were characterized by their slopes, intercepts, their associated standard deviations, the correlation coefficients r, and p-values.

The selected ions used for quantitation were mass-to charge ratio (m/z) of 45 (base peak) for DGBE, and m/z 172 for the IS. The column temperature control program was: solvent delay 3.0 min at 100 °C; hold for 0 min, ramp at 25 °C/min to 280 °C, and hold for 3 min. Dilution into a working linear range with water solvent was performed when necessary. The analyte standard concentrations in water solvent with 2.4 μg/mL IS ranged from 0 (blank), 0.095, 0.95, 9.5, 38, 67, and 95 μg/mL.

Permeation methodology—The ASTM test protocol with 2.54-cm Pyrex permeation cells in the closed-loop mode without recirculation (Figure 1) was followed with some modifications: the temperature of permeation was 35 °C; two challenge half cells were used as noted above instead of the challenge/collection half cells; and sampling was done without collection solvent replenishment.

Test specimens were cut out from the palm areas of the glove material. The test pieces were checked for micro-holes (Frazier physical (Mathews and Que Hee 2016) and microscopic examinations). The gloves were then conditioned at 54 ± 3% relative humidity at 25 ± 1 °C for 24 hr. After conditioning, the glove specimens were removed, test patches cut with scissors, and their thicknesses (micrometer) and infrared reflectance spectra (Avatar 360, RoboteX Inc., Jerseyville, IL) were obtained.

The test piece(s) (outer surface(s) facing the challenge chamber) were then mounted between the PTFE gaskets of the exposed area and sealed by the flanges, with the nuts tightened to a uniform torque that prevented leaks. For double gloving simulation, two pieces were used instead of one. The assembled cells were placed in clamps and inserted into the water bath. The water bath was maintained at 35.0 ± 0.4 °C with a shaking speed of 8.52 ± 0.05 cm/sec to eliminate concentration gradients in the collection solvent. At the start of the 30 min equilibration period at 35 °C, 10 mL of triply deionized water was added to

the collection cell. The test chemical was added at time zero to the challenge cell, and the mixing restarted. Permeation testing occurred over 8-hr and 100 μL samples were taken with a 100 μL Eppendorf pipet with long tips at times (moving tray stopped) into pre-chilled 1-mL vials that varied depending on whether the steady state or the breakthrough time was to be measured. Samples were taken every 5–10 min to define t_n after an initial exploratory run where sampling was done at hourly intervals. No more than 1.0 mL was sampled in total from each permeation cell to ensure constant coverage of the glove material with collection solvent on shaking. The samples were weighed at room temperature to ascertain the exact mass of the sample that was taken. The glove samples were reconditioned at the original conditions before re-measuring all of the parameters. All permeation cells were in triplicate and with a blank (air challenge).

The analyte mass in the collection side was calculated by multiplying the injected sample mass by the permeation cell collection solvent volume in μL at the sampling time divided by two. The total mass collected in the collection side (corrected for mass removed by previous collection) divided by the exposed surface area was then plotted versus sampling time from zero time in minutes to generate the permeation curves for each individual glove tested. The sampling time interval where the permeation reached 250 ng/cm^2 was determined to be the normalized breakthrough time t_n. The time period of steepest slope was identified as the steady state permeation period and its slope and standard deviation obtained through linear regression. The lag time t_l was calculated from this linear regression equation for the time when the injected mass divided by exposed area was zero. The diffusion coefficient D was then calculated from Equation (1) (Schwope et al. 1988):

$$D = l^2/6t_l, \tag{1}$$

where l is the initial thickness in cm, t_l is the lag time in minutes, and D is in cm^2/min.

The mean and standard deviation data for each triplicate set for each nitrile glove type was then calculated.

Statistical analyses

Linear regression was used to characterize linear relationships, including standard deviations of the slopes and intercepts as well as defining the correlation coefficients r and p-values for GC-MS internal standard analysis data that involved area ratios versus injected mass.

The *Student* t-test was used to test the differences in means for all triplicate permeation experimental data, for example, thickness for swelling for each glove before and after permeation, and average t_n, P_s, and D for each nitrile glove type. The threshold p-value was p 0.05. These were obtained with Microsoft Excel 2007 software (Microsoft Corp. Redmond, WA).

Results and discussion

The GC-MS chromatograms showed the analyte peak at 8.45 min relative to the IS peak at 12.93 min for a total run time of 13.2 min. The linear working range was 0.095 μg/mL to 95 μg/mL with p 0.05.

The permeation curves plotted as mass/exposure area permeated versus permeation time had the shape of the lower half of a sigmoid curve. None reached the asymptote but all contained a steady state period. They produced Nelson Type A plots of permeation rate versus permeation time (Nelson et al. 1981). Table 1 contains the averaged individual glove permeation data (t_n range, P_s, and D) for each glove type, and the mean thicknesses before and after permeation.

Thicknesses

The coefficients of variation CV (% relative standard deviations) of the conditioned palm pieces before permeation were all 10% or below, double KB being 10% and single KB at 8.2% being the highest with the other CVs being less than 3.1%. The same trends were found for thicknesses after permeation.

The before and after permeation thicknesses of single and double SB and single KB were not statistically different at p 0.05. The average thicknesses of single and double KP and KS differed statistically at p 0.05 from each other and also from single and double SB and KB. Thus, for the single layers using the before data, SB = KB KP > KS.

The average degree of material swelling for each glove type was found to be less than 10% CV with single KB being the highest at 9.3% (though statistically significant at p 0.05) and the rest having values between 1.3% (single KS) to 7.7% (double KB). This signified that Fick's First Law of Diffusion described the permeation data and that the calculated D values from Equation (1) were therefore valid (Schwope et al. 1988). This was also supported by microscopic and Frazier examination that no micro-holes could be detected, and that the conditioned before and after inner glove surfaces had the same ATR-FTIR spectra.

Normalized breakthrough times

The average t_n for single layers resulted in SB = KB > KP > KS relative to statistical significance at p 0.05. Similarly, for the double layers, SB > KB = KP > KS. If the midpoint of each range is chosen, the t_n factors (double-layer t_n/single-layer t_n) for each nitrile type are: SB, 4.0 ± 1.2, CV = 30%; KB, 3.2 ± 1.1, CV = 34%; KP, 4.7 ± 1.3, CV = 28%; and KS, 7 ± 8, CV = 110%. The factors ranged from 3.2 (KB) to 7 (KS) with CVs ranging from 28% for KP to 110% for KS, the average of the latter also being 1.5–2.2 times greater than the other averages. The grand mean and standard deviation is 4.7 ± 1.6 with a CV of 34%. Outlier analysis at p 0.01 (Snedecor and Cochran 1991) allowed KS data to be ignored. The adjusted grand mean becomes 4.0 ± 0.8 with CV 20% for the t_n factors for SB, KB, and KP that do not show statistical differences and are therefore from the same data population. KS, the thinnest material, was the most difficult to produce flat layers so while

no micro-holes were detected post-permeation, the results could be related to a layering technique artifact that might have allowed enhanced DGBE channeling.

The t_n of most of the glove data were in the "Good" range (10–59 min) according to Kimberly-Clark "splash" criteria (Kimberly-Clark Professional 2009). The exceptions were single-layer KS (t_n were in the 0–5 min range that overlaps the Kimberly-Clark "Poor" (1–9 min) and "Not Recommended" (<1 min) classifications), and single-layer KP (t_n range 5–10 min that overlaps the "Poor" and "Good" classifications; Kimberly-Clark Professional 2009). Kimberly-Clark had no KS data for DGBE. While t_n and t_s might differ or be close (Mathews and Que Hee 2017), the t_n and t_s factors should be independent of BT definition, being unitless. This enables comparison of the present factor data with factors based on different definitions of breakthrough time discussed in the introduction. A factor analysis based on t_s should yield about the same factors especially since t_n and t_s are probably not too different as for cyclohexanol (Mathews and Que Hee 2017).

Similar literature double layering experiments with natural rubber latex disposable gloves resulted in BTs that were about 17 times longer than for a single layer for 70% isopropyl (Maekelae et al. 2003a) and for 25% tetramethyl ammonium hydroxide in water (Su et al. 2013), and in no permeation for various formalin solutions (Maekelae et al. 2003b), carmustine solutions (Klein et al. 2003), or for 17 antineoplastic drugs at patient injection concentrations (Capron et al. 2012).

It is expected that different glove types, thicknesses, and chemicals will produce different t_n factors. The present results do support the previous literature results that double layering will impede permeation. This will not be so, however, when the solvent degrades the glove material.

Steady-state permeation rates

The average P_s increased in the following order for single layers relative to p 0.05: SB < KP < KB < KS. Similarly, the order for double layers was: SB = KB < KP < KS. The single-layer/double-layer P_s factors are: SB, 3.4 ± 0.6, CV = 20%; KB, 7 ± 3, CV = 40%; KP, 2.8 ± 0.2, CV = 7%; and KS, 4.4 ± 0.5, CV = 10%. The P_s factors ranged from 2.8 (KP) to 7(KB), with KB being most imprecise at CV = 40%. The grand mean and standard deviation of 4.4 ± 1.9 has a CV of 43%. Ignoring KB data using the same outlier detection method for the t_n factors produced an adjusted grand mean of 3.5 ± 0.8 with CV 20% for SB, KP, and KS, these three P_s factors not being statistically different and the KB outlier rejectable (Snedecor and Cochran 1991). Why the KB P_s factor is so much higher is unknown but may be related to acrylonitrile content differences or surface finishing processes during glove production or a mixture of reasons. The acrylonitrile contents of the SB, KB, KP, and KS glove outer surfaces reported elsewhere (Mathews and Que Hee 2017) are, respectively, in percent, 13 ± 2, 12 ± 1,17.2 ± 0.7, and 17.1 ± 0.8. The inner surface acrylonitrile contents were, respectively, 9.8 ± 0.5, 12 ± 1, 12.1 ± 0.7, and 12 ± 1. KB was the only glove to have the same acrylonitrile content at the outer and inner surfaces. Since thickness measurements for KB were the most imprecise, probably thickness variation also caused some of the imprecision.

Since disposable gloves are used primarily for "splash" protection and immediately disposed of, there has been no need for P_s data. However, some workers may keep on wearing the disposable gloves, especially if they are in short supply.

The sole literature report on the quantitative effect of double gloving on P_s involved natural rubber disposable latex gloves against 25% tetramethyl ammonium hydroxide aqueous solution where P_s was 3.6 times lower (Su et al. 2013). It is expected that different glove types and different thicknesses will produce different P_s factors, a definite research area.

Comparison and significance of t_n and P_s factors

The t_n and P_s factors measure the extra resistance to permeation that a double-layer offers relative to a single layer at the same conditions. The adjusted grand mean for t_n factors of 4.0 ± 0.8 does not differ statistically at p 0.05 from the adjusted grand mean P_s factor of 3.5 ± 0.8, assuming the data are normally distributed which is certainly not the case with the unadjusted data.

The translation of t_n and P_s factors to the field is complicated by the fact that permeation cell testing of glove pieces does not reflect conditions when whole gloves are worn and where finger and clenching forces that deform the glove material are not accounted for by any of the ASTM, EN, and ISO permeation standards that merely rank permeation data relatively at the same conditions (Banaee and Que Hee 2019). While the temperature of 35 °C used in the present study is realistic (as employed also for ASTM D6978-05 for disposable gloves and chemotherapy agents), gentle forces on the glove material are also provided by the shaking water bath technique as indicated previously (Mikatavage et al. 1984).

A protection factor is defined as the exposure concentration when a worker is not protected divided by the exposure concentration when protected at the same conditions. The concept is used commonly for respirators and less commonly for glove research. Layering t_n and P_s data are related to "enhanced" protection factors if layering data reflect field data as assumed by the studies quoted in the introduction.

Diffusion coefficients

The average D for single layers did not differ statistically at p 0.05. For the double layers, there was no statistical difference at p 0.05 except KB > KS. The single-layer/double-layer average D factors are: SB, 1.13 ± 0.18, CV = 16%; KB, 1.25 ± 0.23, CV = 18%; KP, 4.5 ± 3.0, CV = 67%; and KS, 1.60 ± 0.38, CV = 24%. Layers of the same material that are saturated are expected to have about the same D, that is, a single-layer D/double-layer D factor of about 1.0. The KP data are the most variable in this regard while the other gloves have an average of 1.3 ± 0.2 with CV = 18%, not far from 1.0. There are no previous data in the literature on the effect of double layering on D.

Conclusions

In summary, this research has shown for the first time that double layering of different types of nitrile disposable glove pieces in a ASTM F739 type permeation cell does increase t_n and generally decreases P_s for a analytically pure organic chemical, DGBE This is also the first

report on the effect of double layering on D. The implication is that double gloving of disposable nitrile gloves in the field against DGBE will be more protective but not necessarily to the same extent as embodied by t_n and P_s factors for double layering in a permeation cell. This is due to human factors involved with finger movement and fist clenching.

The present results can be best directly applied to situations where pure or nearly pure DGBE is being used: in analytical chemistry laboratories; in formularies; and in industrial reactors where various purities of technical grade chemical are used. The higher the content of DGBE in formulations the more likely are the current permeation results applicable. There needs to be much more research done on the permeation of its mixtures. The method of characterizing the quantitative effect of double layering through BT and P_s factors can be applied to other systems. The limitations of the method need to be defined for different work-places and work practices, and the types of chemicals and gloves.

Acknowledgments

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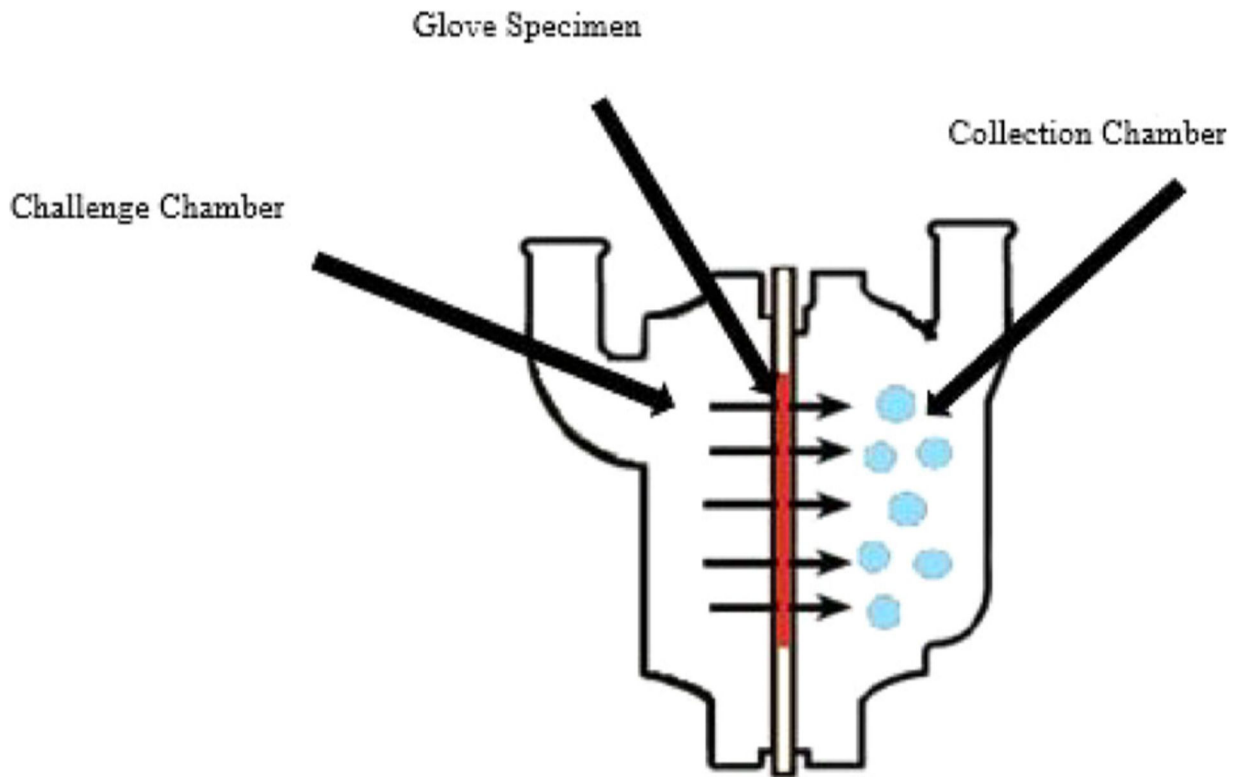Snedecor GW, Cochran WG. 1991. Statistical methods, 8th ed. Ames (IA): Iowa State University Press; p. 278–280.

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Figure 1.
Schematic diagram of the 2.54 diameter pyrex permeation cell in its closed-loop configuration without recirculation that is held in a moving tray shaking water bath at 35 °C and a shaking speed of 8.36 ± 0.09 cm/sec. Pyrex stoppers seal the outlets during the permeation and samples are taken from the collection side after stopping the moving tray and removing the stopper from the collection side outlet.

Table 1.

Permeation of diethylene glycol mono-n-butyl ether through double layers and a single layer of Safeskin Blue (SB), Kimtech Blue (KB), Kimtech Purple (KP), and Kimtech Sterling (KS) on the average normalized breakthrough times at 250 ng/cm^2 (t_n), average steady state permeation rates (P_s), and average diffusion coefficients (D) in triplicate experiments at 35 °C.

| Glove Type | Layers | Thickness, μm | | t_n, min | P_s, mg/cm^2/min | D, cm^2/min |
		Before	After			
SB	1	132(3)	141(2)	10–15	14(1)	1.56(0.03)
	2	262(3)	282(5)	45–55	4.1(0.4)	1.4(0.2)
KB	1	130(10)	140(10)	10–15	23(5)	2.2(0.3)
	2	300(30)	320(30)	35–45	3.3(0.5)	1.67(0.06)
KP	1	113(2)	119(1)	5–10	15.2(0.5)	6(2)
	2	216(7)	228(7)	30–40	5.4(0.3)	1.4(0.4)
KS	1	80(1)	81(1)	0–5	34.3(0.2)	2.0(0.2)
	2	158(3)	167(3)	15–20	7.8(0.8)	1.2(0.2)

The quantities in parentheses are standard deviations of the mean for triplicates.