

The Effect of Distribution on Product Temperature Profile in Thermally Insulated Containers for Express Shipments

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An uninterrupted cold chain is a continual series of storage and distribution activities that maintain a specific temperature or temperature range. Cold chain solutions typically involve excessive packaging to ensure that the desired product temperature is maintained through the distribution process, thereby increasing the logistics-related costs. There is a myriad of solutions available for shipping temperature-sensitive products, including those constructed with a variety of packaging materials as well as refrigerants. Although static characteristics for thermally insulated packaging solutions such as the R-values of package systems as well as the melting points and heat absorption rates of various refrigerants have been studied in the past, none of the past studies have evaluated the effect of comprehensive distribution on the reliability of the cold chain packaging solutions. This research was undertaken to study the temperature profiles for factors such as different densities for a given thickness of thermally insulating material, wall thicknesses and distribution environments for four different types of materials—polyurethane, virgin expanded polystyrene, recycled content expanded polystyrene and vacuum-insulated panels. The temperature range of 2 °C-8 °C, critical for pharmaceutical drugs and vaccines, was targeted. An interesting regression-based finding was that the interaction between the R-value and the wall thickness significantly influenced the length of time the thermally insulated packages stayed in the desired range of 2 °C-8 °C. The findings of this study will be decisive in designing cost-efficient and practical single-use cold chain transportation solutions for temperature-sensitive products.

INTRODUCTION

Cold chain refers to the transportation of temperature-sensitive products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of these shipments.¹ Thermal abuse is a primary concern during the distribution of temperature-sensitive goods such as pharmaceutical, food and chemical products. Thermally insulated packaging can maintain product temperatures within acceptable ranges and slow down the deterioration of the product in the distribution environment until it reaches the consumer. In addition to a high resistance to the transfer of heat (R-value), a good thermally insulating material must have various characteristics, depending on the application. For packaging applications, low cost, low moisture susceptibility, ease of fabrication and transportation, consumer appeal and mechanical strength are the most relevant characteristics.²

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Various types of temperature-controlled packaging systems including containers and refrigerants are commonly used to provide an uncompromised passage of the product through distribution.

The reliance on the cold chain has continued to gain importance during the past few decades. Within the pharmaceutical industry for instance the testing, the production and the movement of drugs rely heavily on controlled and uncompromised transfer of shipments. A large fraction of the pharmaceutical products that move along the cold chain are in the experimental or developmental phase.¹ Clinical research and trials are a major part of the industry that costs millions of dollars, but one that also experiences a failure rate of approximately 80%.¹ According to the Healthcare Distribution Management Association, of the close to 650 billion dollars in bio-pharmaceutical distribution in 2005, approximately 40% were drugs that are temperature sensitive.¹ This makes the cold chain responsible for transporting approximately 260 billion dollar investment.¹

If these shipments should experience any unanticipated exposure to variant temperature levels, they run the risk of becoming ineffective or even harmful to humans. According to Alistair Black, Project Director at Aptuit Clinical Supplies Europe, 'Maintaining the chemical and therapeutic integrity of investigational medicinal products poses special cold chain challenges, because clinical trials require multiple small shipments to as many as 300 study sites worldwide'.³ Similar arguments can be made for other temperature-sensitive products such as perishables (processed or otherwise) and chemicals. Food products, for example, when stored at temperatures higher than 5 °C provide a rich growth environment for both spoilage organisms and pathogens, resulting in greater risk of both economic loss and an outbreak of food-borne illness.⁴

Temperatures, a packaged product experiences during distribution, need to be addressed by an optimum cold chain packaging solution. During the past several decades, numerous proficient cold chain packaging systems have evolved. Although the carrier-controlled thermal chains provide refrigerated trailers for the transportation of goods and the two-way systems use reusable shipping containers, the one-way shipment of temperature-sensitive products in single-use packaging has been critical in the cold chain and often relies on expedited shipping service providers such as FedEx, UPS and DHL.

Being able to ensure that a shipment will remain within a temperature range for an extended period depends largely on the type of container that is used and the refrigeration method adopted. Factors such as the duration of transit, the size of the shipment and the ambient or outside temperatures experienced are important in deciding what type of packaging is required. They can range from small insulated boxes that require dry ice or gel packs to a 53-ft reefer that has its own powered refrigeration units.

The choice of distribution system is governed by payloads, transit time, temperature sensitivity of the product, customer acceptance and cost.¹ One-way systems have emerged as the most popular option for their ease of application. Insulated containers provide insulation using different packaging material combinations and refrigerants to maintain the desired temperatures and preserve product quality.

Of the limited published researches evaluating the R-values (resistance to heat flow) of package systems and the melting points and heat absorption rates of refrigerants,⁵⁻⁷ none have focused on the effect of these values as related to distribution simulation. In other words, all of the past studies have been conducted under 'near-static' and not 'dynamic' environments. The latter presents unique challenges to cold chain solutions for temperature-sensitive products in terms of mechanical shocks, vibration, compression, cyclic temperature and humidity exposure, and so on.

This research studied the temperature profiles for factors such as different densities for a given thickness of packaging material, wall thicknesses and distribution environments. Refrigerants and insulated packages available in the market today were used in this study.

Objectives

Laboratory-based studies were conducted to compare the effectiveness of thermally insulated packaging in the range of 2 °C-8 °C because of the following factors:

- Different densities for a given thickness of packaging material Expanded Polystyrene (EPS)
- Different thickness of material types: EPS, recycled EPS, vacuum-insulated packaging (VIP) and polyurethane

R-values of insulated shipping containers
Distribution environment testing based on ASTM/ISTA protocols

MATERIALS AND METHODS

Materials

Thermally insulated containers. Twenty different types of thermally insulated containers were obtained for this study, as shown in Table 1 and Figure 1. Material types, wall thicknesses, densities, total internal surface area and total internal volumes are shown in Table 1, and the types of tests conducted are shown in Table 2.

Refrigerant. Phase 5TM/ 5 °C Phase Change Material (PCM) was obtained from TCP Reliable (Edison, NJ). This PCM, enclosed in high-density polyethylene containers, measured 13.97 x 13.97 x 2.54 cm and weighed 300 gm ± 1.5% each. Filled with a proprietary material that undergoes phase change at 5 °C (middle of the 2 °C-8 °C range), these PCM cartridges were frozen at 0 °C ± 2 °C, as per the manufacturer's recommendation, before all tests. A 0.30 m³ capacity Haier model HMCM106EA chest freezer (New York, NY, USA) equipped with Johnson Controls' model A419 digital temperature controller (Milwaukee, Wisconsin, USA) was used to condition the refrigerant for 48 h. With a set point temperature range of -34 °C to 104 °C and a differential adjustment of 1 °C to 3 °C, the digital temperature controller was operated by overriding the internal thermostat of the freezer.

Product. To control any variability in the product (payload) used for this study, twenty 20 ml borosilicate test tubes measuring 1.60 x 15.01 cm were used. A sample holder to hold these test tubes in place was constructed from E-flute-corrugated fiberboard. The test tubes were filled to the 20 ml level and plugged with tapered rubber stoppers measuring 1.91-1.40 cm in diameter. A centrally located test tube in the payload pack was instrumented by inserting the temperature monitor probe through the rubber stoppers. The payload was conditioned at 2 °C for 48 h. Figure 2 shows the payload, the PCM arrangement around the payload, an instrumented test tube and an example of the loaded container.

Temperature monitors. TempTale® Model 4 temperature monitors from Sensitech Inc. were used to monitor the temperature inside the insulating containers tested.⁸ The temperature monitors had flexible probes that were inserted into the package to monitor and record the temperatures. The devices were factory calibrated with the accuracy tested to NIST traceable standards. The Sensitech Temp Tale 4 temperature monitors have a resolution of 0.1 °C and measured in the -30 °C to 70 °C range. The sensor accuracies were ±0.55 °C from -18 °C to 50 °C. The monitors were setup to record the temperatures at every 30 s for this research.

Methods

Two different tests were performed: an R-value measurement and a study of the effect of distribution to the temperature profiles inside the shippers. All test configurations were conducted in triplicate and the details are provided below.

R-value measurement. The resistance to the flow of heat through an insulating package designated as the system R-value was calculated using ice-melt tests.⁷ The test is based on the principal that 1 kg of regular ice must absorb 335 kJ of heat to melt. By placing a known quantity of ice inside the container, the rate of heat transfer into the container was calculated from the quantity of ice melted at the end of test.

To conduct the ice melt test, the ice was first preconditioned for the actual test. A sufficient quantity of regular ice (~2.5 kg) was placed in a nonmetallic bucket and allowed to melt. After an interval of time (~2 h), the water from the bucket was drained. This ensured that the ice was at its melting temperature of 0 °C uniformly and not at the freezer temperature where it was stored.

The bucket was then placed at the centre of the container, which was then closed tightly with tape, as per manufacturer's instructions. The containers were stored on a shelf at ambient temperature for 12 h.

Table 1. Specifications of thermally insulated containers studied.

Container ID	Vendor	Material	Wall thickness (cm)	Density (kg/m ³)	Inside dimensions L x W x H (cm)	Total surface area (dm ²)	Internal volume (dm ³)
E46UPS	Thermosafe	Polyurethane foam	2.54		25.4 x 25.4 x 20.3	33.6	13.1
E36UPS	Thermosafe	Polyurethane Foam	5.08		27.9 x 20.3 x 17.8	28.5	10.1
E38UPS	Thermosafe	Polyurethane Foam	7.62		27.9 x 21.6 x 17.8	29.7	10.7
42VIP-UPS	Thermosafe	V acuum-Insulated Panels	1.27		22.9 x 20.3 x 25.4	31.2	11.8
37VIP-UPS	Thermosafe	V acuum-Insulated Panels	2.54		25.4 x 20.3 x 20.3	28.9	10.5
F-900	Cold Ice	Virgin EPS	2.54	20.0	24.1 x 21.6x21.0	29.6	10.9
F-105	Cold Ice	Virgin EPS	3.81	20.0	20.3 x 16.5 x 19.7	21.2	6.60
F-115	Cold Ice	Virgin EPS	5.08	20.0	21.0x21.0x21.0	26.4	9.20
Fageradala 1.75-1.25-100	Fageradala	EPS, 100% RC	4.45	20.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.75-1.25-90	Fageradala	EPS, 90% RC	4.45	20.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.75-1.25-80	Fageradala	EPS, 80% RC	4.45	20.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.75-1.5-100	Fageradala	EPS, 100% RC	4.45	24.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.75-1.5-90	Fageradala	EPS, 90% RC	4.45	24.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.75-1.5-80	Fageradala	EPS, 80% RC	4.45	24.0	26.7 x 20.3 x 15.9	25.8	8.60
Fageradala 1.5-1.25-100	Fageradala	EPS, 100% RC	3.81	20.0	22.9 x 22.9 x 16.5	25.6	8.63
Fageradala 1.5-1.25-90	Fageradala	EPS, 90% RC	3.81	20.0	22.9 x 22.9 x 16.5	25.6	8.63
Fageradala 1.5-1.25-80	Fageradala	EPS, 80% RC	3.81	20.0	22.9 x 22.9 x 16.5	25.6	8.63
Fageradala 1.5-1.5-100	Fageradala	EPS, 100% RC	3.81	24.0	22.9 x 22.9 x 16.5	25.6	8.63
Fageradala 1.5-1.5-90	Fageradala	EPS, 90% RC	3.81	24.0	22.9 x 22.9 x 16.5	25.6	8.63
Fageradala 1.5-1.5-80	Fageradala	EPS, 80% RC	3.81	24.0	22.9 x 22.9 x 16.5	25.6	8.63

RC, recycled content.

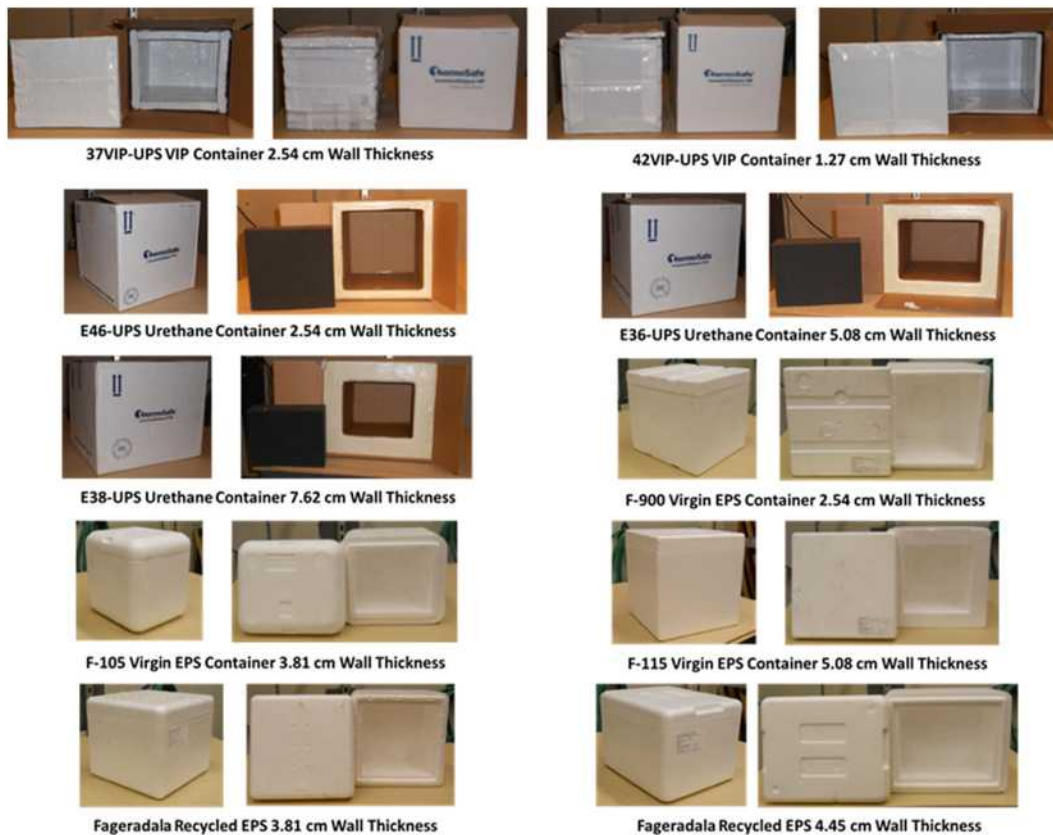


Figure 1. Examples of thermally insulated containers studied.

The shelf was solid, and five of six sides of the container were exposed to still air. The average temperature was 23 °C with a maximum deviation of ± 2 °C. At the end of the test, containers were opened, and water was collected from the buckets. The weight of water collected was recorded to calculate the melt rate.

The previously mentioned procedure was repeated for a test interval of 24 h. The aim of the experiment was to have some ice left in the bucket. Melt rate is the weight of water collected in kilograms divided by the test time in hours. A constant temperature difference was maintained for as long as there is some amount of ice left inside the bucket because the ice maintains a constant temperature of 0 °C as it melts.

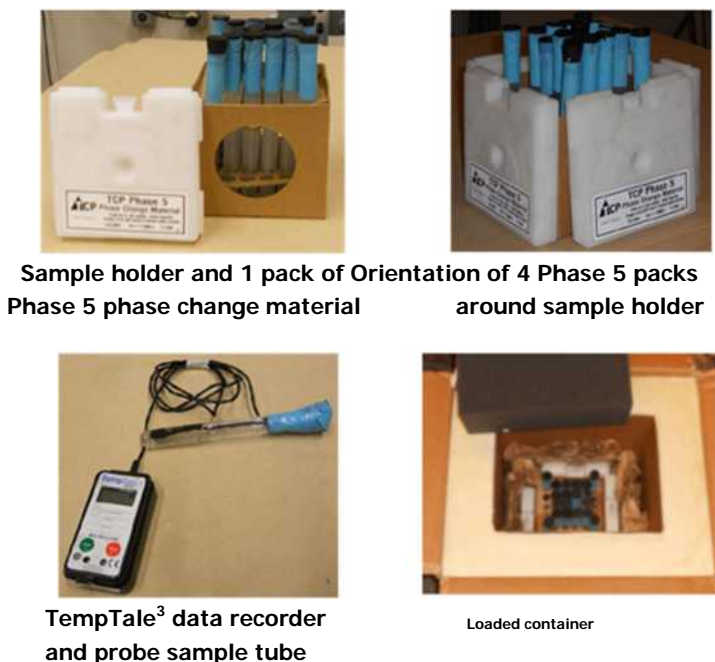
The system R-value for the packages was calculated using the following equation⁷

$$\text{System R-value} = \frac{(\text{Surface area})(\text{Temperature difference})}{(\text{Melt rate})(\text{Latent heat})} \quad (1)$$

Distribution simulation testing. ASTM and ISTA test protocols were used to conduct simulation of distribution scenarios experienced by packages in the express single parcel environment. The ISTA 7D Procedure⁹ (Thermal Controlled Transport Packaging for Parcel Delivery System Shipment) is a development test to evaluate the effects of external temperature exposures of individual packaged products shipped through a parcel delivery system. It can be used for the development of temperature-controlled transport packages made of any material and for individual or comparative performance analysis of standard or insulated transport packages against normally encountered conditions. It is designed to measure the relative ability of a package to protect a product when exposed to test cycles that simulate both the range and the time of exposure to ambient temperature conditions.

Table 2. Test sequence for ISTA Procedure 7D.⁸

Sequence no.	Test category	Test type	Test level
1	Atmospheric preconditioning (ASTM D 3103)	Temperature	Storage conditions for the product and each package element for 24 h, 0 min
2	Shock conditioning (ASTM D 5276)	Drop	Height varies with packaged-product weight (76 cm)
3	Atmospheric (ASTM D 3103)	Temperature	First cycle period of selected test profile (shown in Table 3)
4	Vibration conditioning (ASTM D 4728)	Random vibration	Overall Grms level of 1.15 (3 h)
5	Atmospheric (ASTM D 3103)	Temperature	Second cycle period of selected test profile (shown in Table 3)
6	Shock conditioning (ASTM D 5276)	Drop	Height varies with packaged-product weight (76 cm)
7	Atmospheric (ASTM D 3103)	Temperature	Remaining cycle periods of selected test profile (shown in Table 3)



Sample holder and 1 pack of Orientation of 4 Phase 5 packs
Phase 5 phase change material around sample holder



TempTale³ data recorder
and probe sample tube



Loaded container

Figure 2. Stages of preparing a loaded container for experimentation.

The ambient conditions in the test facilities were monitored throughout the study by using temperature monitors and were maintained at $23\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$ and $50 \pm 5\%$ relative humidity.

Table 2 presents the test sequence for ISTA Test Procedure 7D with sequences 3,5 and 7 being required and 1, 2, 4 and 6 being optional.⁹⁻¹² This research included all the optional testing. This sequence represents the typical distribution hazards encountered by small packages in the express shipping environment.

Table 3 shows the cyclic conditioning profile for a 48 h domestic express small package freight transport (air) used in this study.

RESULTS AND DISCUSSION

R-value measurement

The results for R-value testing are reflected in Figures 3 and 4 below. By material type, the performance of the containers was observed to be vacuum-insulated panels, polyurethane, recycled content

Table 3. Cyclic test profile for 48 h domestic express small package freight transport (air).⁸

Summer profile		
Hot shipping and hot receiving		
Temperature	Cycle/ramp period	Cycle/ramp period hours
22 °C (72 °F)	1	0-6
to	2	2 h ramp
45 °C (113 °F)	3	2 h at temp
to	4	2 h ramp
30 °C (86 °F)	5	12-24
to	6	2 h ramp
45 °C (113 °F)	7	2 h at temp
to	8	2 h ramp
30 °C (86 °F)	9	30-48

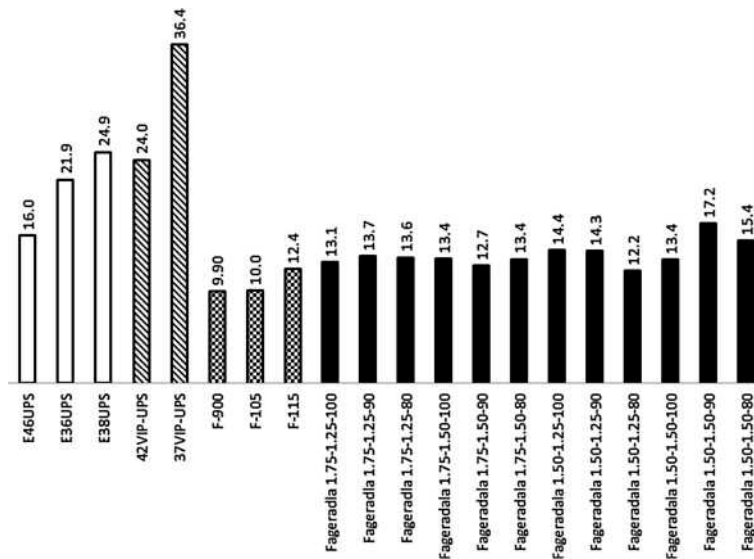


Figure 3. R-Value for all containers studied.

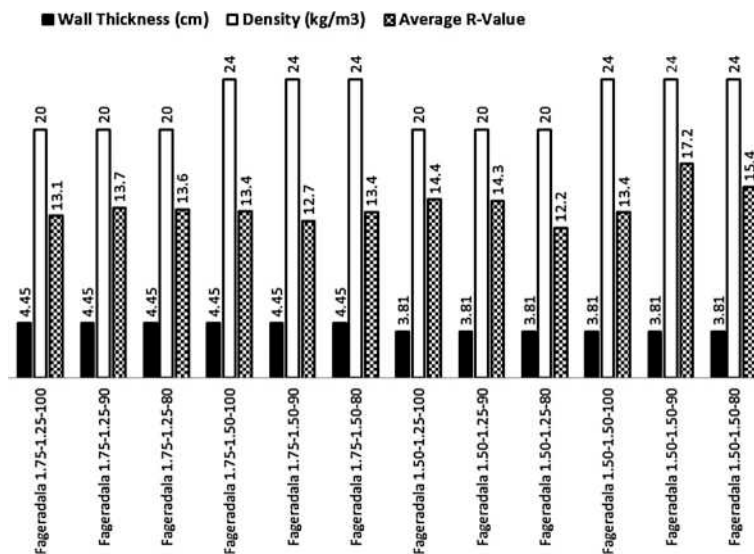


Figure 4. R-Value result comparison with wall thickness and densities of recycled content EPS containers.

EPS and virgin EPS in decreasing order. Wall thickness, not considering the recycled content EPS containers, was observed to be directly proportional to the observed R-values. Considering the containers with 2.54 cm thick walls, those with VIP performed 128% and 267% better than the polyurethane and virgin EPS, respectively. For the two containers studied with 5.08 cm thick walls, containers with polyurethane performed approximately 77% better than those made with virgin EPS.

Twelve EPS containers with recycled content were used in this study. Figure 4 shows the effects of wall thickness and foam density on the observed R-values for these containers.

The R-value was observed to decrease by approximately 7.95% when comparing the containers with 4.45 cm thick walls to those with 3.81 cm. When comparing the R-values against recycled content, containers with 90% recycled content had the highest value of 14.5. The 80% and 100% recycled content containers displayed 5.80% and 6.28% lower R-values, respectively, as compared with the 90% recycled content containers.

Distribution simulation testing (regression analysis)

The objective of the regression analysis is to capture the effect of R-value and wall thickness on the length of time (duration) the thermally insulated packages stayed in the desired 2 °C-8 °C range. Table 4 shows the sample frequency distribution for three replicates each of the 20 different types of containers tested for the durations of maintaining the 2 °C-8 °C range. As can be seen, 15 containers (25%) maintained the temperature of the product between this range for up to 6 h, 18 containers (30%) from 6 to 12 h, 10 containers (17%) from 12 to 18 h and 6 containers (10%) from 18 to 24 h. Eleven of the containers (18%) tested exceeded the 24 h period.

Also included in Table 4 are the average R-values and average wall thickness for each duration range. For example, for the duration in the range up to 6 h, the average R-value is 13.6 and the average wall thickness is 4.19. In general, higher R-values and lower wall thickness are associated with higher durations. Although these summary measures are informative, a multiple regression model allows a more formal analysis because the summary measures cannot capture the two effects simultaneously. Also, as noted later, the regression model also allows us to capture the influence of the interaction between R-values and wall thickness.

We first estimate the log-linear model specified in the following equation:

$$\text{Model 1 : } \ln(\text{duration}) = \beta_0 + \beta_1 R - \text{value} + \beta_2 \text{wall thickness} + e \quad (2)$$

Here, the dependent variable is the natural logarithm of duration in the 2 °C-8 °C range. We used the log transformation of the duration variable to ensure that the predicted duration is always nonnegative; it also enabled us to capture interesting nonlinearities in the model. Further, various model selection measures, including the coefficient of determination, indicate that the log-linear model is superior to its linear counterpart. In the second column of Table 5, we present the regression results of model 1.^{a2}

Parameter estimates are at the top half of Table 5, with the p-values in parentheses; an asterisk (*) represents significance at the 5% level. The lower part of the table contains goodness-of-fit measures, S_e is the standard error of the estimate and R^2 and adjusted R^2 represent the usual and adjusted coefficient of determination. Predictions for the log-linear model are made as $\exp(\beta_0 + \beta_1 x_1 + \dots + \beta_k x_k + S_e^2/2)$, where β_j is the estimated coefficient of the predictor variable x_j .

From Table 5, we note that both the R-value and the wall thickness variables are significant at the 5% level; however, R-value exerts a positive influence whereas wall thickness is negatively related

Table 4. Summary measures.

Duration (h)	Observations	Average R-value	Average thickness
0-6	15	13.6	4.19
6-12	18	14.1	4.52
12-18	10	15.2	4.13
18-24	6	17.2	3.18
24 or more	11	22.9	3.23

Table 5. Log-linear regression model results.

Variable	Model 1	Model 2
Constant	1.99 (0.00)*	5.41 (0.00)*
R-Value	0.07 (0.00)*	-0.08 (0.15)
Wall thickness	-0.20 (0.02)*	-1.14 (0.00)*
R-Value*wall thickness		0.04 (0.01)*
SE	0.82	0.77
R^2	0.44	0.61
Adjusted R^2	0.42	0.59

◆represents significance at the 5% level

to duration. This is consistent with the summary measures in Table 4. We note that the estimated coefficients in the log-linear model allow us to capture the predicted effect in percentages rather than in levels. For example, the coefficient estimate of 0.07 of R-value in model 1 suggests that a one unit increase in R-value increases the predicted duration by 7%. Similarly, a one unit increase in wall thickness decreases the predicted duration by 20%.

In Figure 5, we used the estimated coefficients of model 1 to simulate the effect of R-value and wall thickness on duration. Predictions for Figure 5 are calculated as $\exp(1.99 + 0.07x_1 - 0.20x_2 + 0.82^2/2)$, where x_1 and x_2 are the simulated values for R-value and wall thickness, respectively.

For instance, for an R-value of 20, the predicted durations are 23.9, 18.6 and 14.5 h for wall thickness of 2.54, 3.81 and 5.08 cm, respectively. The values increase to 33.5, 26.0 and 20.3 h as the R-value increases to 25. Consistent with the model estimates, the duration increases as R-value increases and/or wall thickness decreases.

We extend model 1 to allow interaction between the R-value and wall thickness variables. In the third column of Table 5, we present the regression results of model 2 described in the following equation:

$$\text{Model 2 : } \ln(\text{duration}) = \beta_0 + \beta_1 R - \text{value} + \beta_2 \text{wall thickness} + \beta_3 R - \text{value} \times \text{wall thickness} + e \quad (3)$$

Model 2 outperforms model 1 on the basis of a lower standard error of the estimate ($0.77 < 0.82$) and a higher adjusted R^2 ($0.59 > 0.42$). Further, whereas the R-value variable is insignificant, its interaction with wall thickness is statistically significant at the 5% level. We present the simulation results with this estimated model 2 in Figure 6. Predictions for Figure 6 are calculated as $\exp(5.41 - 0.08x_3 - 1.14x_2 + 0.04(x_1 * x_2) + 0.77^2/2)$, where x_3 and x_2 are the simulated values for R-value and wall thickness, respectively. For an R-value of 20, the predicted durations are 30.0, 20.5 and 14.0 h for wall thickness of 2.54, 3.81 and 5.08 cm, respectively. These values increase to 34.7, 30.9 and 27.5 h as the R-value increases to 25. Interestingly, wall thickness has a negative influence on duration except when it is accompanied by high R-values. At R-values greater than 27.3, the predicted duration is the highest for wall thickness of 5.08 cm.

CONCLUSIONS

This research was undertaken to study the temperature profiles for factors such as different densities for a given thickness of thermally insulating material, wall thicknesses and distribution environments for four different types of materials—polyurethane, expanded polystyrene, recycled expanded polystyrene and vacuum-insulated panels. The temperature range of 2 °C-8 °C, critical for pharmaceutical drugs and vaccines, was targeted.

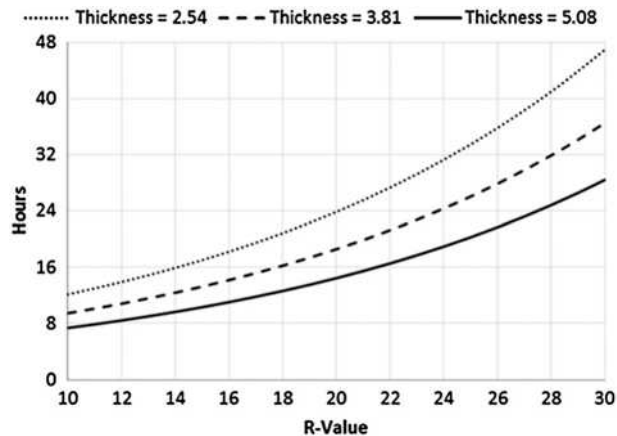


Figure 5. Simulated duration in the 2 °C-8 °C range.

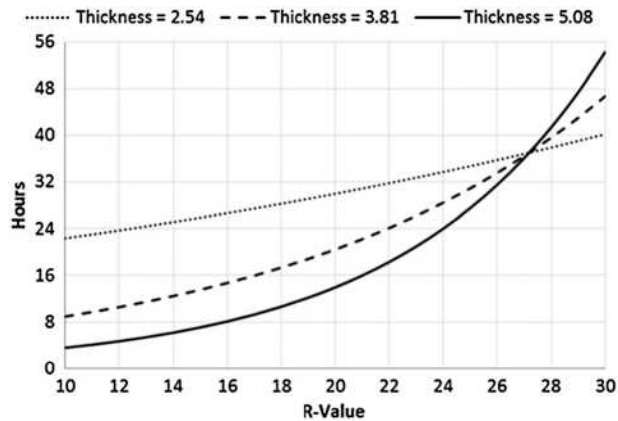


Figure 6. Simulated duration in the 2 °C-8 °C range with cross products.

By material type, the R-value-based performance of the containers can be ranked in a decreasing order as vacuum-insulated panels, polyurethane, recycled content EPS and virgin EPS. Wall thickness, not considering the recycled content EPS samples, was observed to be directly proportional to the observed R-values. Considering the containers with 2.54 cm thick walls, those with VIP performed 128% and 267% better than the polyurethane and virgin EPS, respectively. For the two containers studied with 5.08 cm thick walls, containers with polyurethane performed approximately 77% better than those made with virgin EPS. Recycled content EPS containers outperformed the virgin EPS containers for all densities and thicknesses studied

The objective of the distribution simulation portion of the study was to capture the effect of R-value and wall thickness on the length of time the thermally insulated packages stayed in the 2 °C-8 °C range. Only approximately 20% of the containers tested were able to maintain the temperature of the product at 2 °C-8 °C for more than 24 h.

The regression results suggest that, in isolation, the R-value and wall thickness variables are significant at a 5% level, where the R-value exerted a positive influence and wall thickness a negative influence. However, the most interesting result pertained to the significant interaction between these variables. It was found to be optimal to use low wall thickness except when it was accompanied by high R-values. This finding could possibly be used by manufacturers of these containers in using greater wall thickness only for materials with high R-values.

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