US 20070186577A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2007/0186577 A1**

(43) **Pub. Date: Aug. 16, 2007**

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(54) **PASSIVELY TEMPERATURE-REGULATED SHIPPING CONTAINER SUITABLE FOR BIOLOGICAL, PHARMACEUTICAL MATERIALS OR FOOD PRODUCTS**

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(21) Appl. No.: **11/355,837**

(22) Filed: **Feb. 16, 2006**

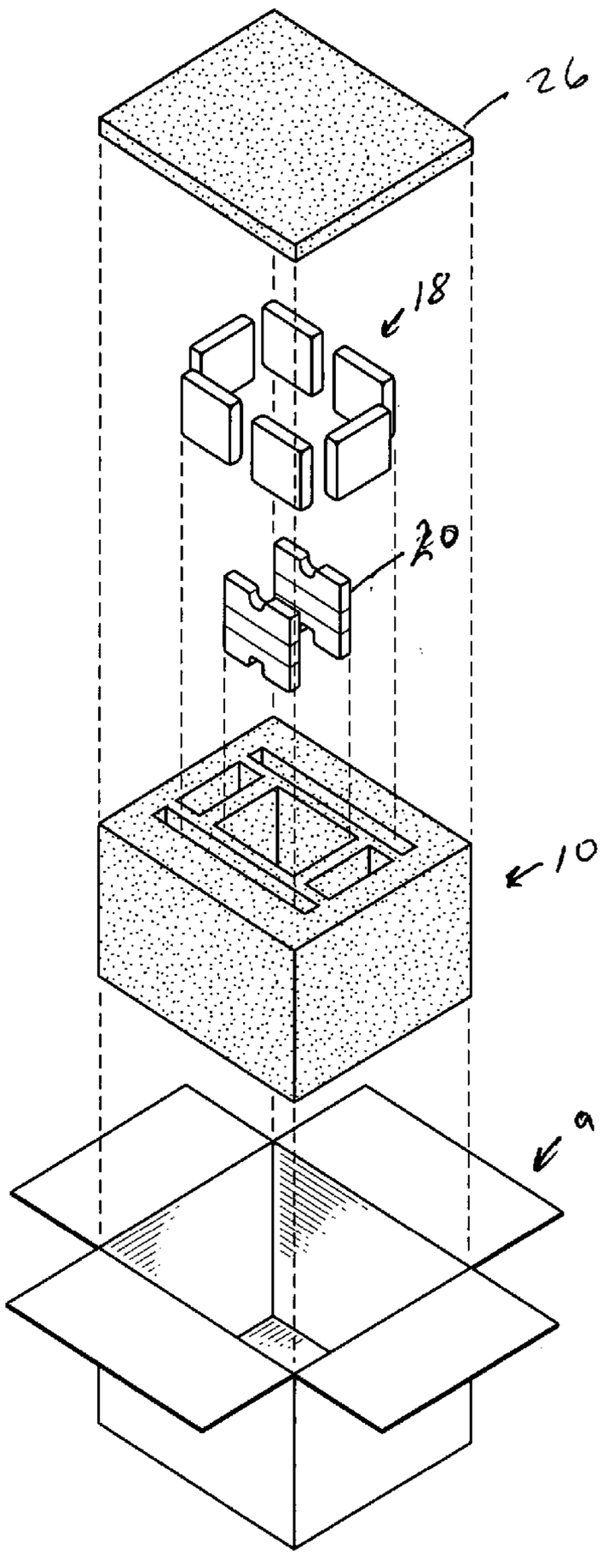
Publication Classification

(51) **Int. Cl.**
F25D 3/08 (2006.01)

(52) **U.S. Cl.** **62/371**; 62/457.2

(57) **ABSTRACT**

Disclosed is a shipping container suitable for use for pharmaceuticals, biological materials, blood or tissues, or food products, having a double-walled multiple-chamber structure, wherein a first phase change material, with a phase change temperature between 2° to 8° C. (and in a preferred embodiment, 5°C.) in a payload chamber, and wherein the container includes one or more first chambers surrounding and sharing a wall with the payload chamber, and housing ice (or ice gel packs). A lid fits over (or is hinged to) the upper edges of the walls to seal the container and the payload.



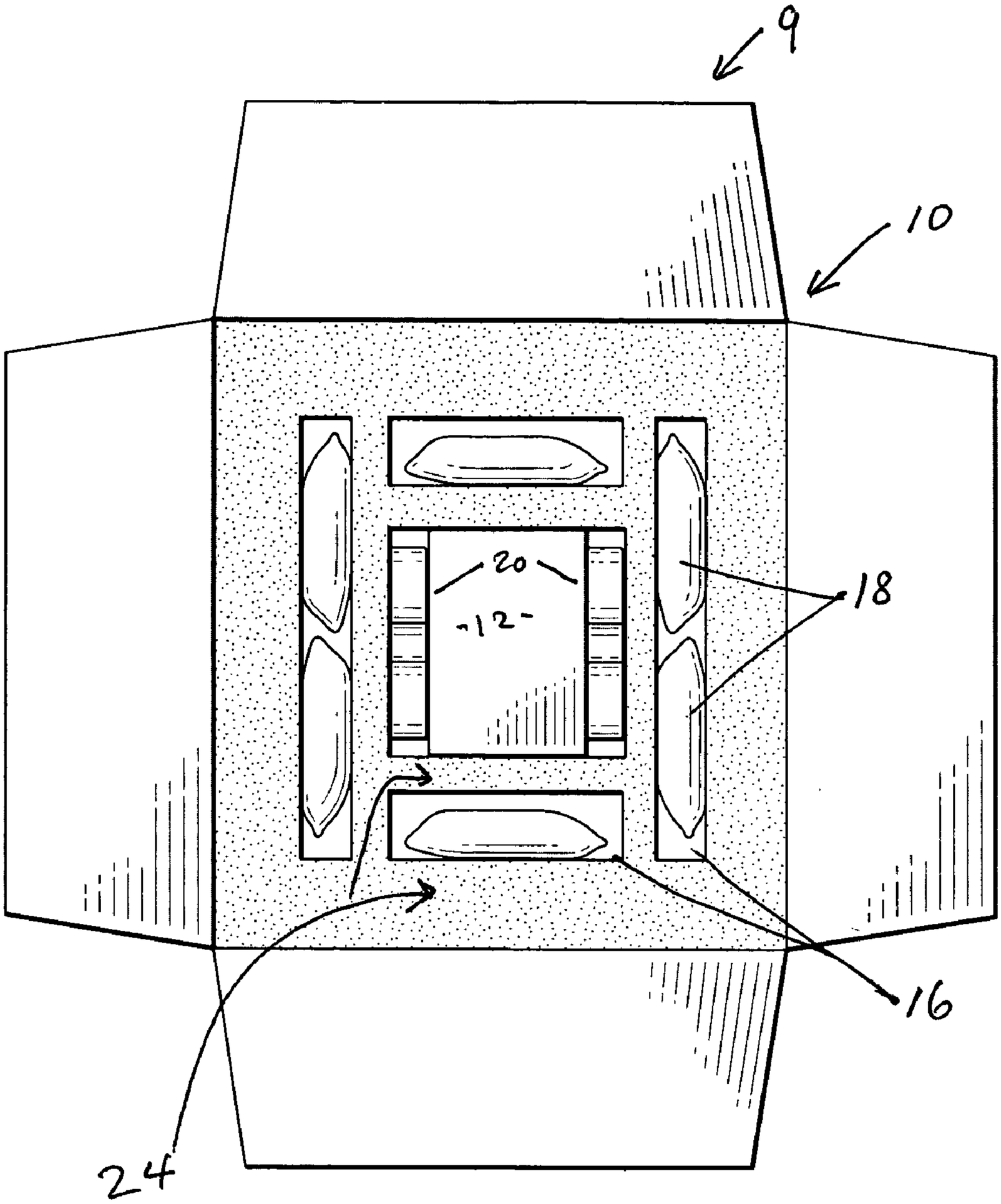


FIG. 1

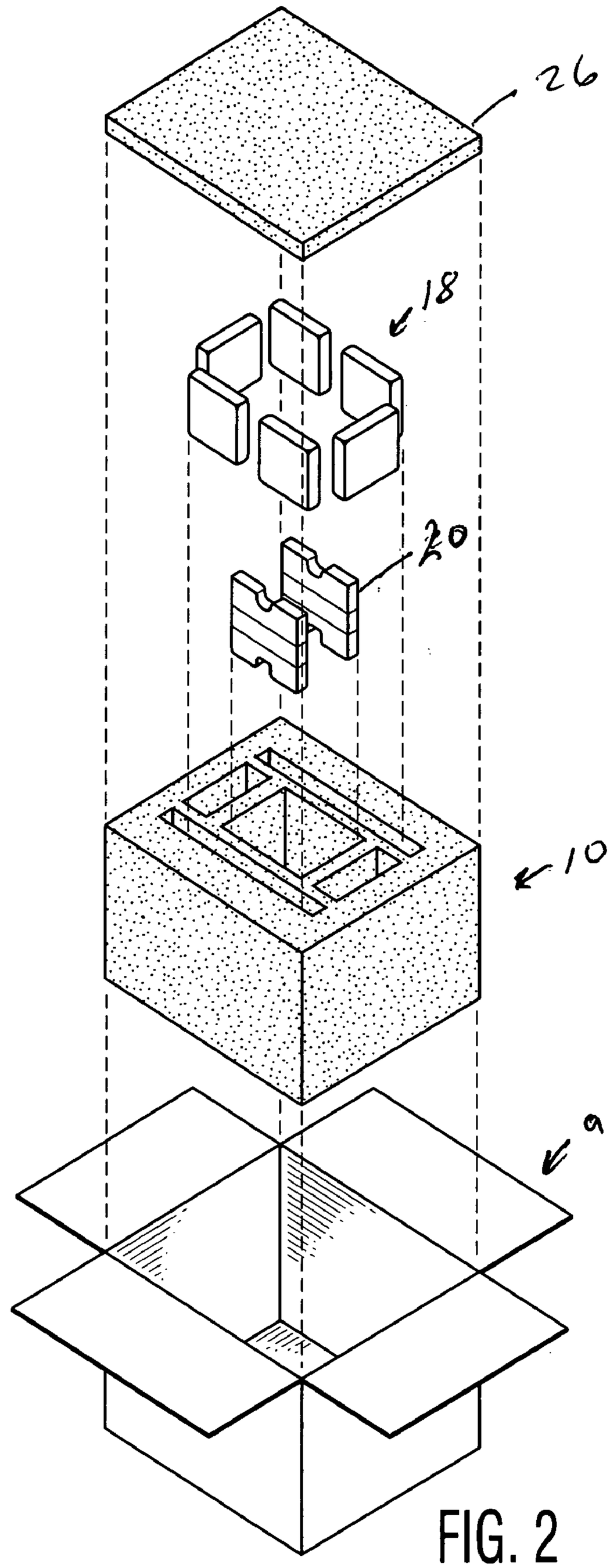


FIG. 2

PASSIVELY TEMPERATURE-REGULATED SHIPPING CONTAINER SUITABLE FOR BIOLOGICAL, PHARMACEUTICAL MATERIALS OR FOOD PRODUCTS

BACKGROUND OF THE INVENTION

[0001] In the pharmaceutical, transplant and food industries, maintaining the temperature of shipped materials at refrigeration levels is necessary for proper preservation of the product. The temperature inside a shipping container can be actively maintained, for example, with a refrigeration unit, but passive regulation is preferred, due to decreased cost and the elimination of the need for a continuous power source during shipment. Any temperature regulation mechanism, however, should be suitable for use in a variety of weather and external temperature conditions, so that the customers do not have to purchase and then use several different passive regulation systems, which compensate for ambient temperature differences in shipment. With such systems, the customers would also be required to predict weather and shipping conditions.

[0002] Passive regulation with conventional means, e.g., ice or ice "gel packs," which keep the temperature near 0° C. cannot maintain a consistent internal refrigeration-like temperature (about 5° C.) in a shipping container. Attempts have been made to enhance temperature regulation at refrigeration levels using a phase change material—with a phase change at or near the desired internal temperature. See, e.g., U.S. Patent Application Publication Ser. No. 2005/0031809, incorporated by reference. The principle is that whether the external temperature rises above or falls below the phase change temperature, the internal temperature is maintained at a relatively consistent level, as the phase change material absorbs internal heat as it liquefies, and releases heat as it freezes. One drawback is that such phase change materials (such as alcohols as disclosed in U.S. Patent Application Publication Ser. No. 2005/0031809) can be relatively expensive. Thus, minimizing their use is desirable to achieve a competitively priced shipping container.

[0003] Given the formula for determining q, the power lost through an insulator:

$$q = \frac{\Delta T}{R},$$

where, ΔT represents the temperature difference across an insulator, and R is the thermal resistance of an insulator (R=L/kA, where L is the wall thickness, k is coefficient of thermal conductivity, and A is the surface area of the insulator), it can be seen that if the insulator is being used to maintain refrigeration temperatures using an internal phase change material with a phase change at about 5° C. the reduction in q for that material, between the case where the ambient temperature is 35 to 45° C. (as can occur in hot summer conditions in the unregulated interior of a railroad car or truck trailer), and where the temperature across the insulator is 0° C. (i.e., ice is on the other side of the insulator), would be between 1/7 and 1/9. Thus, ice could be used in an appropriately constructed container/insulator system to reduce quantities of phase change material needed. Minimizing use of phase change material is desirable to achieve a competitively priced shipping container.

SUMMARY OF THE INVENTION

[0004] Disclosed is a shipping container suitable for use for biological materials, blood or tissues, or food products, having a double-walled multiple-chamber structure, wherein a first phase change material, with a phase change temperature between 2° to 8° C. (and in a preferred embodiment, 5° C.) is placed in a payload chamber, and wherein the container includes one or more first chambers surrounding and sharing a wall with the payload chamber, and housing ice (or ice gel packs). In a preferred embodiment, the first chamber(s) outer wall is the container exterior wall. A lid fits over (or is hinged to) the upper edges of the walls to seal the container and the payload.

[0005] The container is preferably made of an insulating material ,e.g., expanded polystyrene (EPS) or urethane, and/or can include a vacuum panel or an air baffle—additional insulating material for the container is optional.

[0006] The advantages of the container include those resulting from the first change material undergoing a phase change near the middle of the 2° to 8° C. range. This temperature range is the standard for shipping pharmaceutical, biological materials and food products. It is insulated (by a wall) from the ice in the first chamber and double-insulated (two walls) from the exterior, thereby minimizing the effects on the first phase change material of exterior temperature, and reducing the required amount of the first phase change material. Suitable first phase change materials include 1-decanol (melting at 5° C.); sometimes a higher phase change material such as 1-dodecanol (melting at 22° C.) may be used for particular purposes. Use of less costly ice or gel packs in the first chambers permits use of these more costly alcohols to be reduced. Moreover, external temperatures encountered in shipment (including whether its shipped in summer or winter) are of lessened concern.

[0007] The container is designed such that the payload, the ice/gel packs and the first phase change material can all be "dropped in" to their respective chambers, from the top, increasing the ease of loading for the user. Other advantages are described below and are apparent from the description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. **1** is a plan view of a shipping container as described herein, without the lid in place.

[0009] FIG. **2** is an isometric view of the container shown in FIG. **1**.

DETAILED DESCRIPTION OF THE INVENTION

[0010] FIG. **1** depicts a shipping container **10**, inside a container **9**, and having a payload chamber **12**, and a series of first chambers **16**. Ice (depicted in the form of gel packs **18**) is placed in the first chambers **16**. Individual containers **20** containing a first phase change material is placed in the payload chamber **12**, which also houses a payload, preferably pharmaceuticals, food or a biological material. Two containers **20** are shown, but more may be used, with four (so that the payload is completely surrounded) being preferred. Suitable phase change materials include those that change solid to liquid in the range of 2° to 8° C. for example, decanol, and other materials including many set forth in US

Patent No. 5,647,226: "Phase change apparatus for animal parts, human body parts, body fluids and culture" (incorporated by reference). It is also possible to use phase change materials outside this range for particular purposes, for example, dodecanol. Instead of ice it is possible to use other materials that melt at a temperature near about 0° C.

[0011] The walls **24** of the container are depicted as one molded unit, e.g., EPS, but they could also be formed from multiple sections, or can have additional insulation added following construction. Additional padding or protective materials for the payload can also be added. The lid **26** (shown in FIG. **2**) can be removable from the top of the container **10** as shown, or hinged or attached otherwise in a manner to permit access to the payload chamber **12** and the first chambers **16**. When the lid **26** is removable as shown, the container **9** is preferably corrugated, and capable of being sealed to hold lid **26** in place.

[0012] Suitable payloads include biological materials, e.g., cells, pharmaceuticals, blood or tissues or food products, or other materials which need temperature-regulated refrigeration during shipment.

[0013] It should be understood that the terms, expressions and features in the drawings shown herein are exemplary only and not limiting, and that the invention scope is defined only in the claims which follow, and includes all equivalents of the subject matter of the claims.

What is claimed is:

1. A shipping container for food product or pharmaceutical, biological materials that require temperature maintenance at refrigeration levels, comprising:

an outer perimeter wall, and an insulating wall surrounded by the outer wall;

one or more first chambers between the interior side of the outer wall and the outer side of the insulating wall, and an inner chamber, designed to accommodate the payload, surrounded by the insulating wall;

a removable lid on one side of the container; and

a lower side opposite the lid; and wherein a material which has a temperature of about 0° C. is positioned in the first chamber, and a phase change material having a solid to liquid phase change temperature in a range from 2° to 8° C. is positioned in the inner chamber.

2. The shipping container of claim 1 wherein the phase change material has a solid to liquid phase change temperature at 5° C.

3. The shipping container of claim 1 wherein the phase change material is decanol.

4. The shipping container of claim 1 wherein the inner surface of the outer perimeter wall and the outer surface of the insulating wall define the first chambers, and the inner surface of the insulating wall defines the inner chamber.

5. The shipping container of claim 1 wherein additional insulating material is positioned in the inner chamber or first chamber, or in both.

6. The shipping container of claim 1 wherein the insulating wall and the outer wall are made of expanded polystyrene, urethane, and/or include a vacuum panel or an air baffle.

7. The shipping container of claim 1 wherein the payload is biological materials, including cells, pharmaceuticals, blood or tissues or food products,

8. The shipping container of claim 1 wherein the removable lid is attached by hinges to a portion of the outer wall.

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