US009810671B2

(12) **United States Patent**
Heacock et al.

(10) **Patent No.: US 9,810,671 B2**
(45) **Date of Patent: *Nov. 7, 2017**

(54) **APPARATUS WITH TIMED COLOR CHANGE INDICATION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/822,240**

(22) Filed: **Aug. 10, 2015**

(65) **Prior Publication Data**

US 2015/0346172 A1 Dec. 3, 2015

Related U.S. Application Data

(60) Continuation of application No. 13/780,050, filed on Feb. 28, 2013, now Pat. No. 9,134,285, which is a (Continued)

(51) **Int. Cl.**
G02C 7/00 (2006.01)
G02C 7/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***G01N 31/229*** (2013.01); ***A61B 17/3211*** (2013.01); ***A61B 90/92*** (2016.02);
(Continued)

(58) **Field of Classification Search**
CPC G02C 7/046; G02C 7/021; G04F 1/00; G04B 47/061; B65D 79/02; B65D 2203/00
(Continued)

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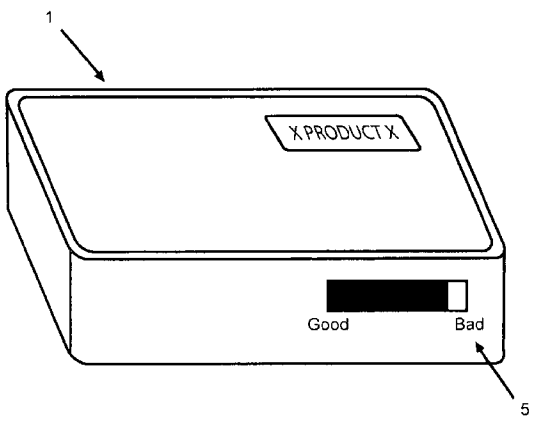
(74) *Attorney, Agent, or Firm* — McAndrews, Held and Malloy

(57) **ABSTRACT**

An apparatus with time controlled color change indication comprises an apparatus includes a disposable, limited or restricted use product and an oxygen sensing color changeable dye disposed on a portion of the apparatus, the dye being translucent or having a first color upon application and for a defined time thereafter and the dye changing color after exposure to oxygen for the defined time. For example, a packaging for containing a product for human consumption has a portion with a color changeable dye disposed thereon. The dye changes color after being exposed to oxygen for a controlled and predetermined period of time indicating that the product for human consumption should no longer be consume or has decreased in freshness, quality of taste or potency.

16 Claims, 12 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 13/688,550, filed on Nov. 29, 2012, now Pat. No. 8,702,237, which is a division of application No. 12/504,107, filed on Jul. 16, 2009, now Pat. No. 8,388,131, which is a continuation of application No. 11/607,298, filed on Nov. 30, 2006, now abandoned.

(51) **Int. Cl.**

G02C 7/04	(2006.01)
G01N 31/22	(2006.01)
A61K 47/22	(2006.01)
A61B 17/3211	(2006.01)
A61M 5/50	(2006.01)
G02C 7/10	(2006.01)
A61B 90/92	(2016.01)
A61B 3/16	(2006.01)
A61M 5/31	(2006.01)
G01D 7/00	(2006.01)
A61M 5/00	(2006.01)
A61B 1/00	(2006.01)
A61B 90/00	(2016.01)

(52) **U.S. Cl.**

CPC ***A61K 47/22*** (2013.01); ***A61M 5/5086*** (2013.01); ***G02C 7/021*** (2013.01); ***G02C 7/04*** (2013.01); ***G02C 7/104*** (2013.01); ***G02C 7/108*** (2013.01); *A61B 1/00062* (2013.01); *A61B 3/16* (2013.01); *A61B 2090/0807* (2016.02); *A61B 2090/0814* (2016.02); *A61M 5/002* (2013.01); *A61M 5/3129* (2013.01); *A61M 2205/583* (2013.01); *G01D 7/005* (2013.01)

(58) **Field of Classification Search**

USPC 351/159.01, 159.28; 368/89; 206/459.1

See application file for complete search history.

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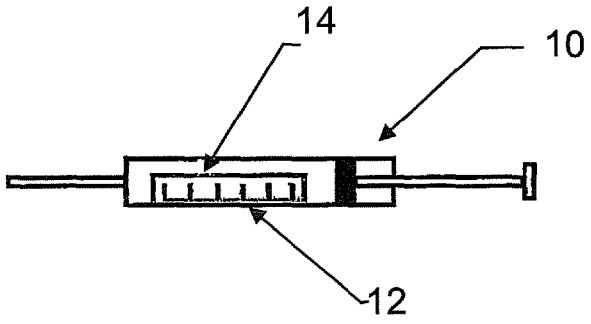
Figure 1



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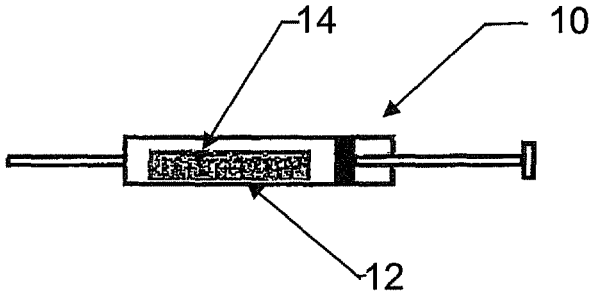

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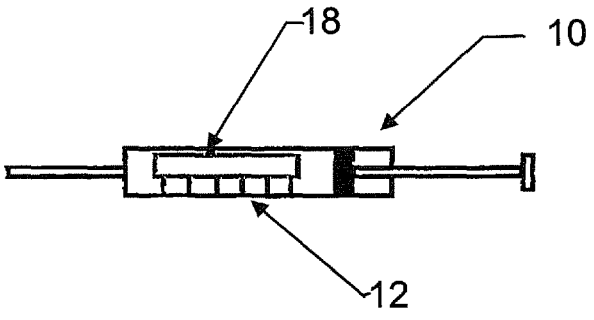

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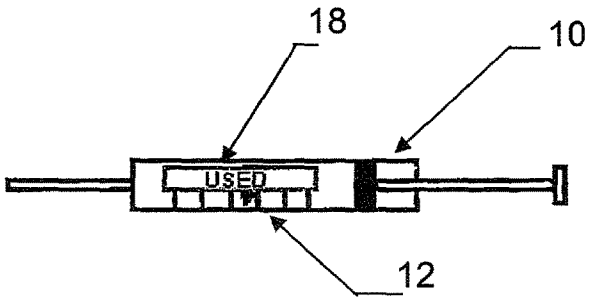

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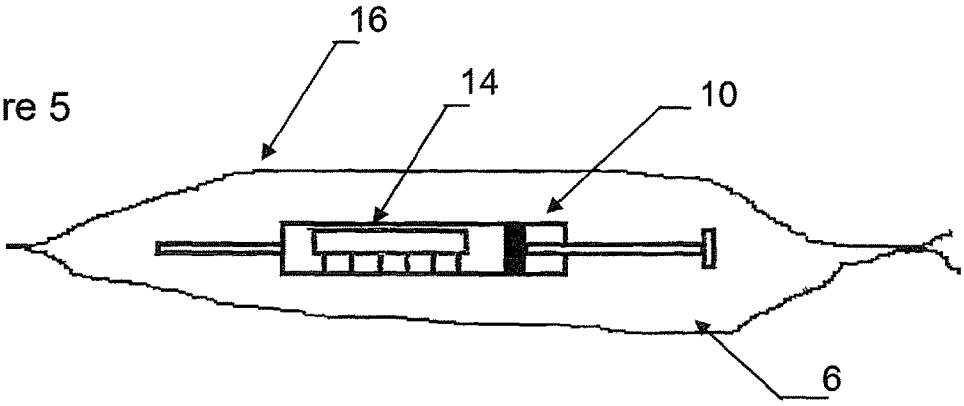

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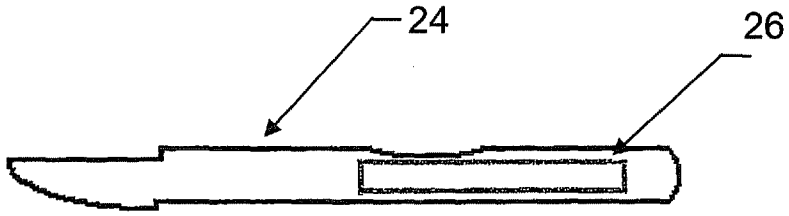

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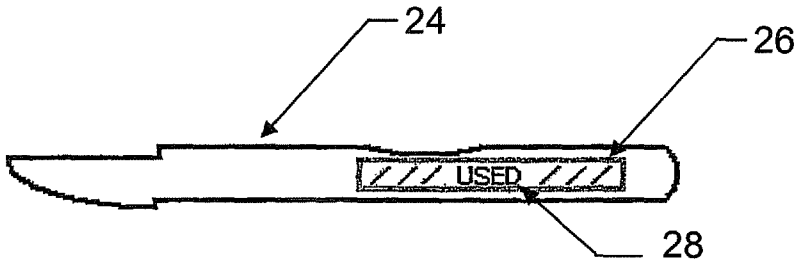

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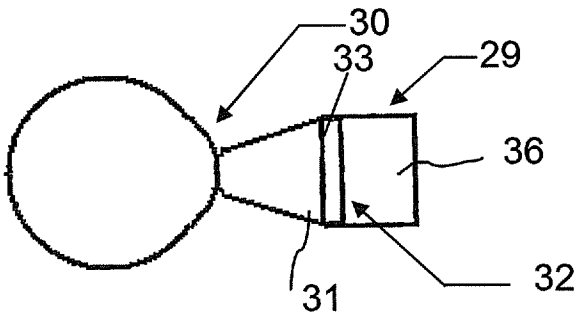

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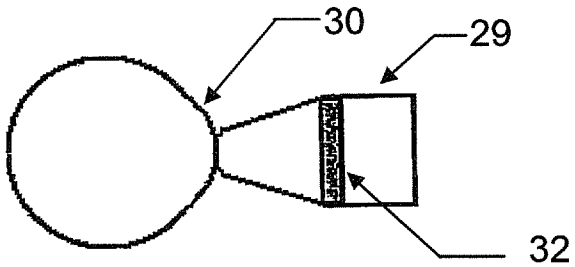

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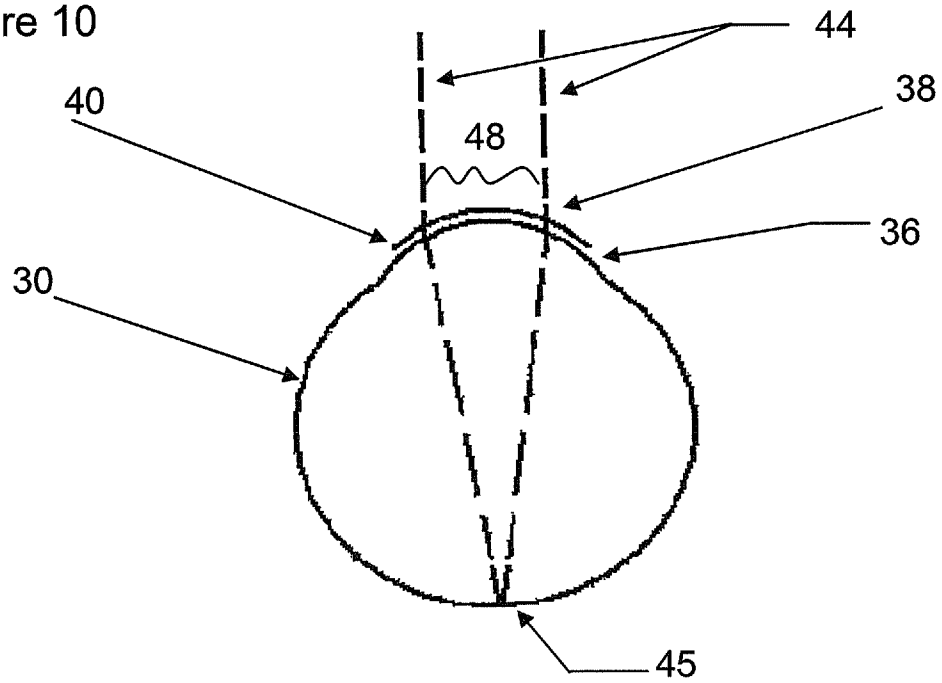

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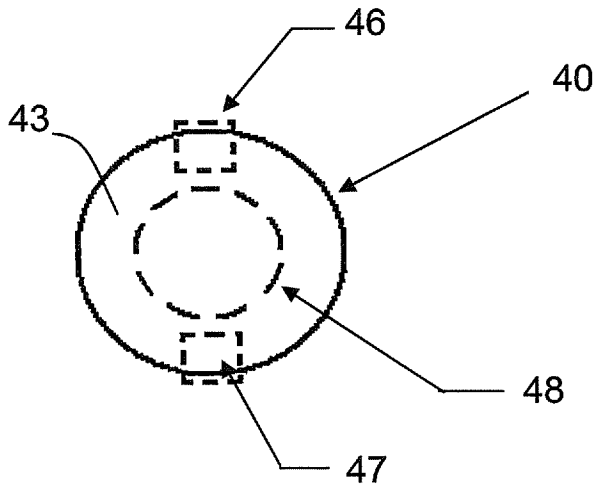

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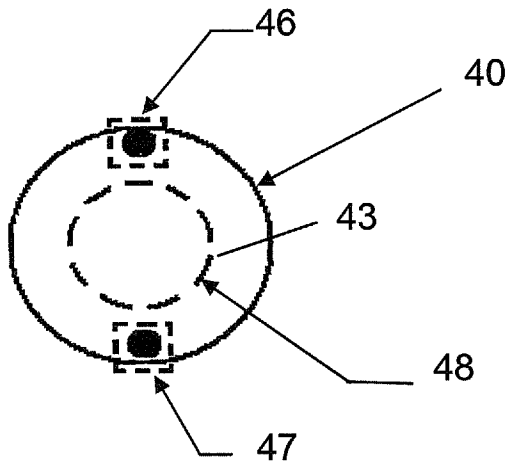

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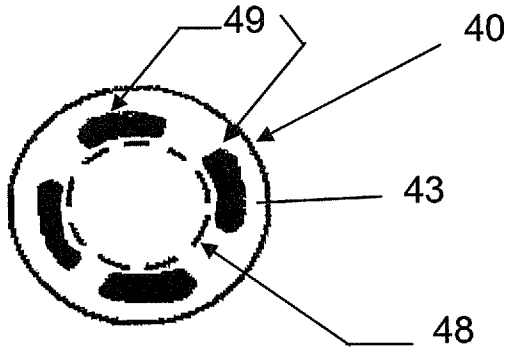

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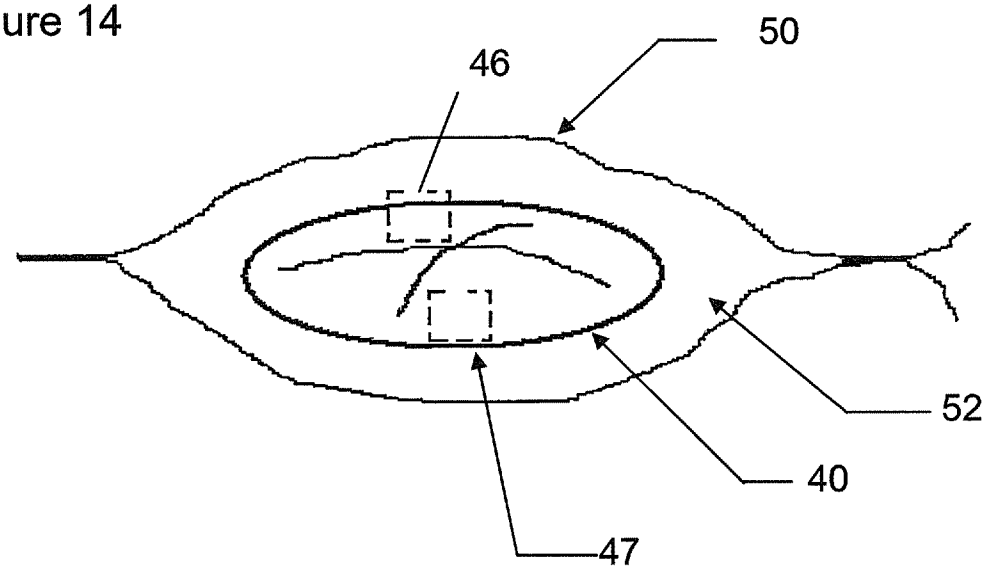

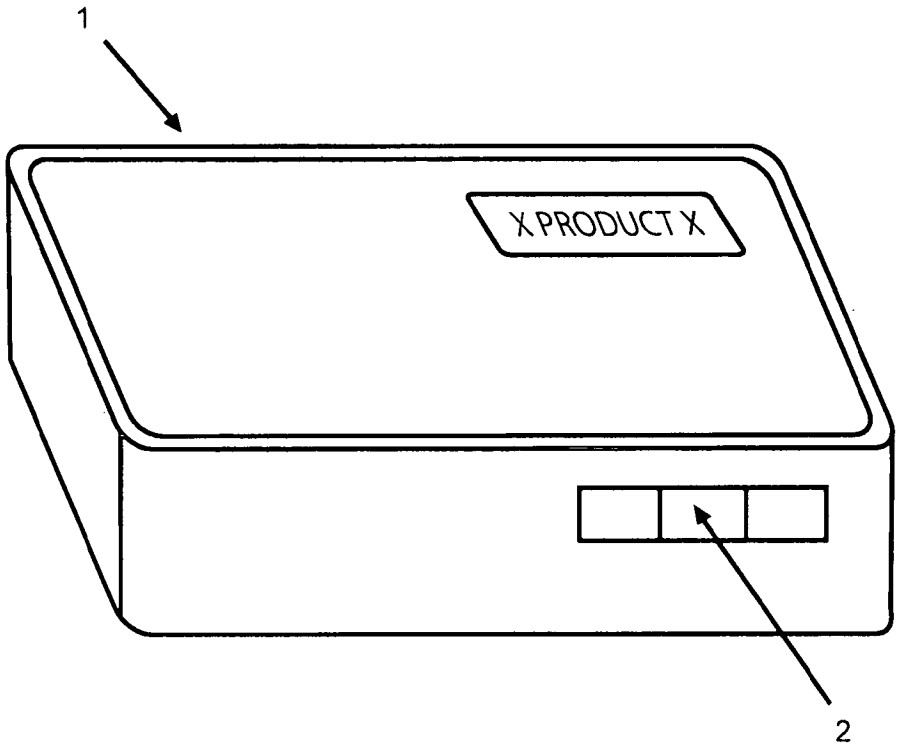

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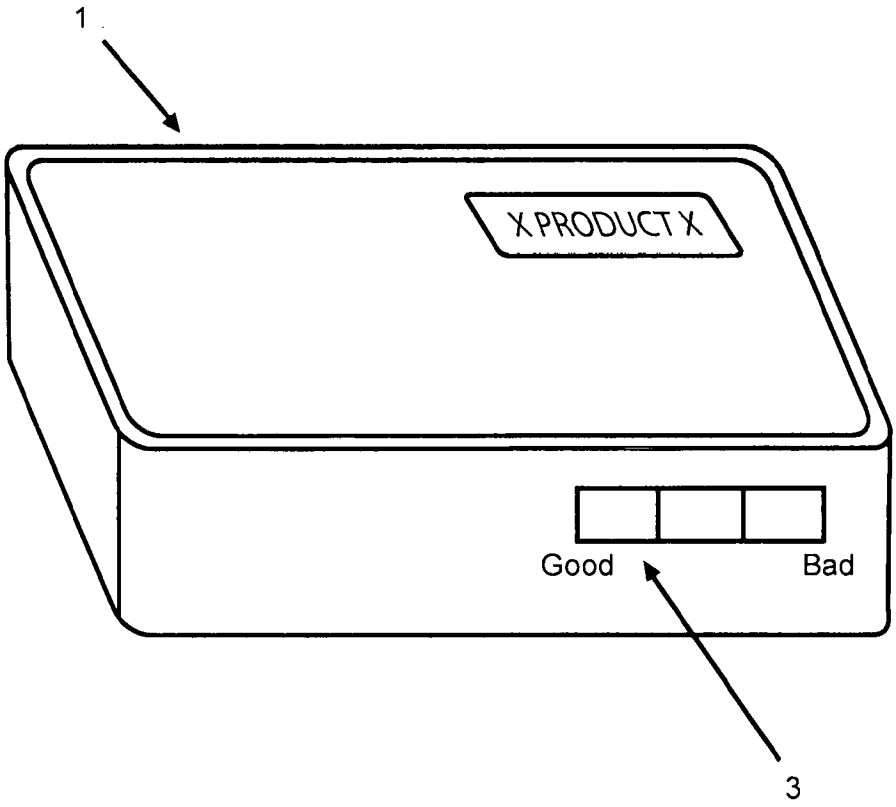


Figure 16

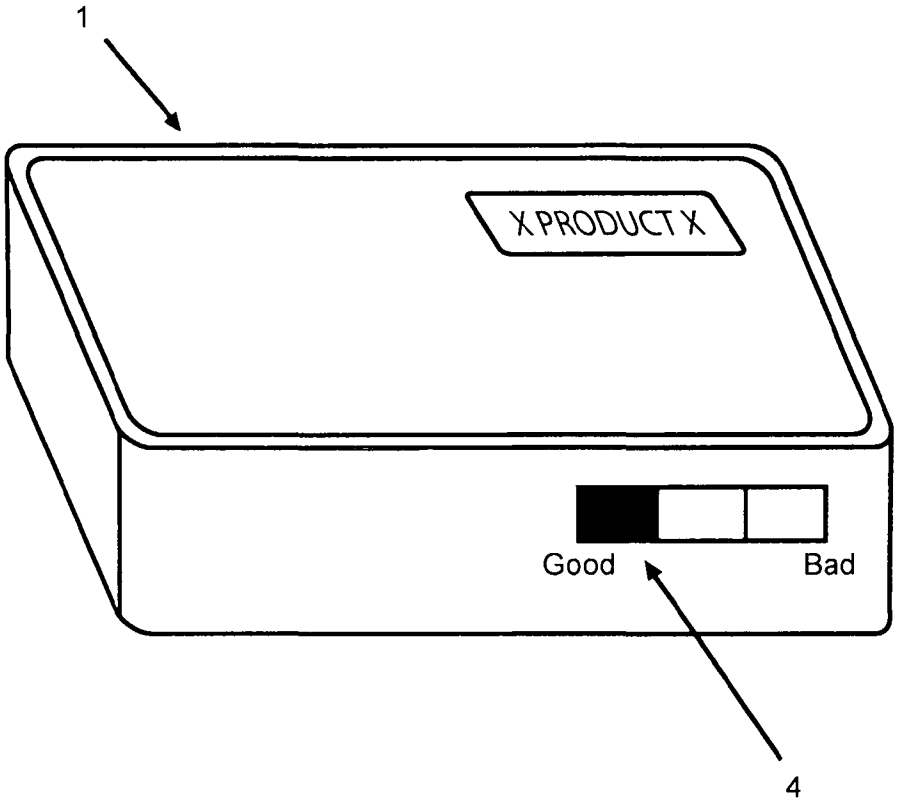
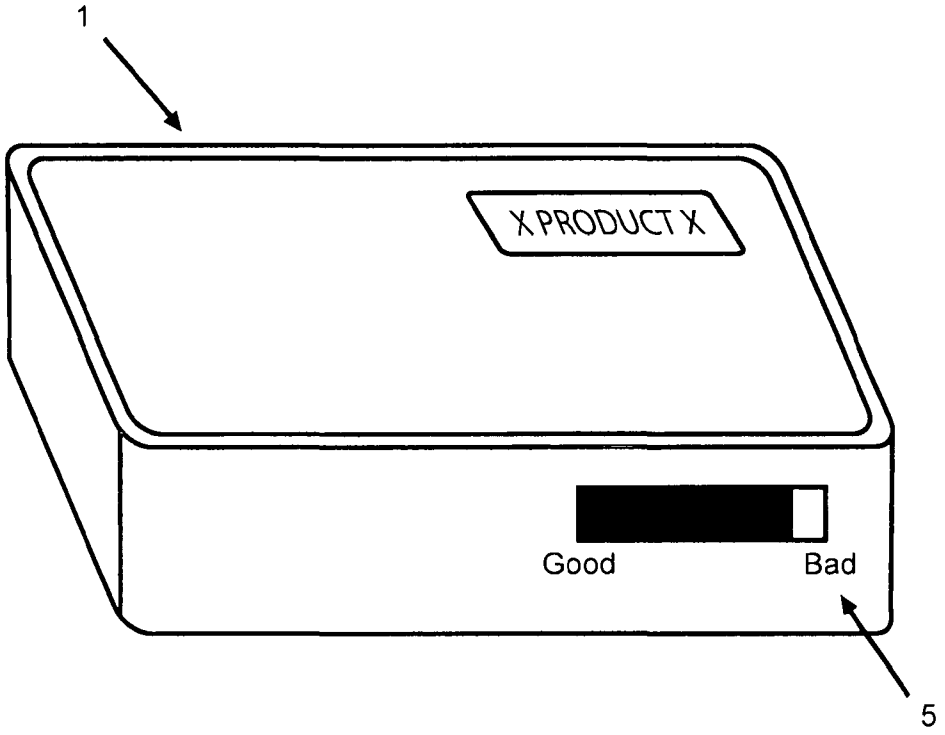


Figure 17



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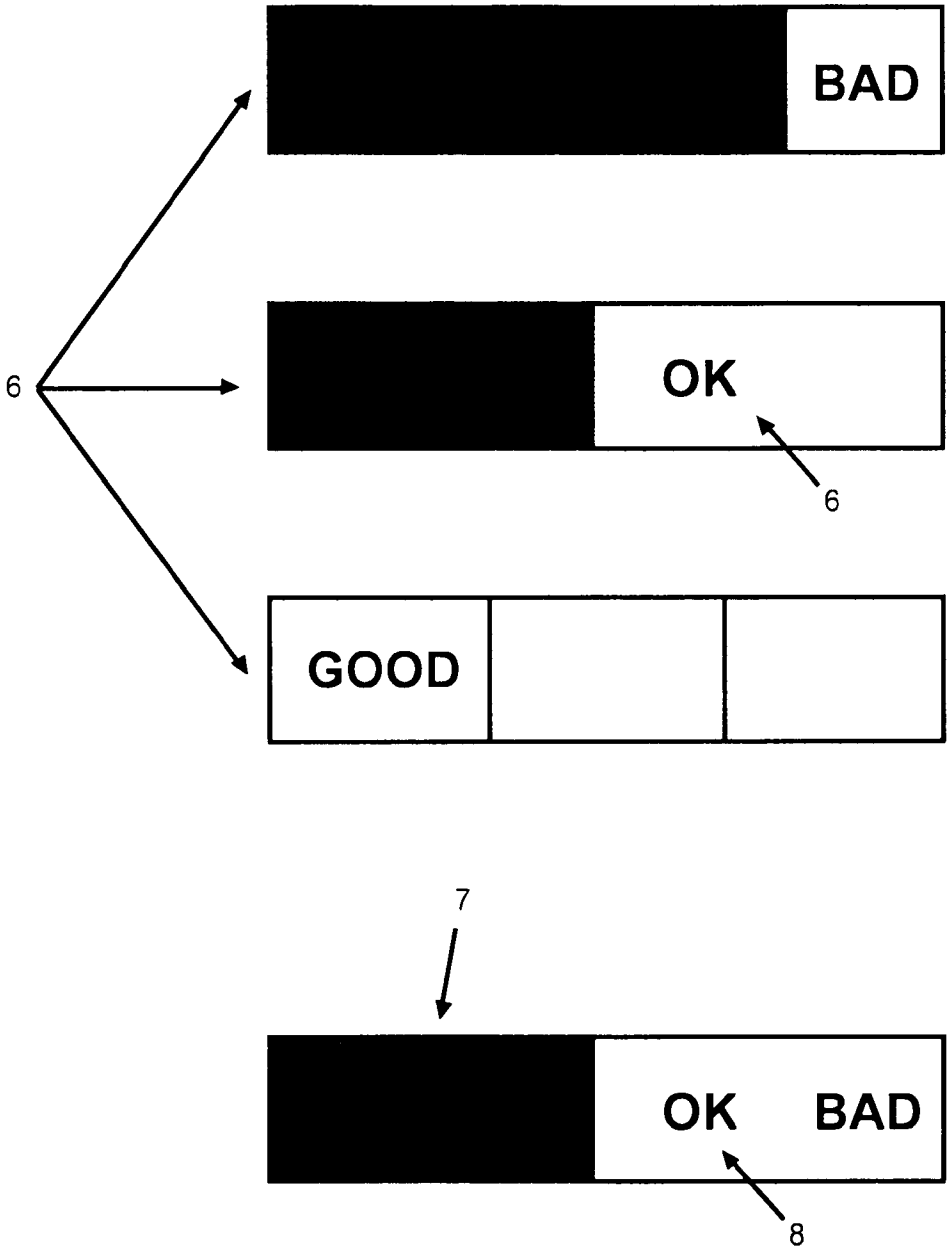

Figure 19

APPARATUS WITH TIMED COLOR CHANGE INDICATION

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is filed as a continuation of Ser. No. 13/780,050, which was filed Feb. 28, 2013, which is a continuation in part of Ser. No. 13/688,550, which was filed Nov. 29, 2012 (now U.S. Pat. No. 8,702,237, issued Apr. 22, 2014), which is a divisional of U.S. patent application Ser. No. 12/504,107, which was filed Jul. 16, 2009 (now U.S. Pat. No. 8,388,131, issued Mar. 5, 2013), which is a continuation of U.S. patent application Ser. No. 11/607,298, which was filed on Nov. 30, 2006. The entire text of the aforementioned applications is incorporated herein by reference in its entirety.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[Not Applicable]

FIELD OF THE INVENTION

The present invention relates to a disposable, limited or restricted use product that can transmit contaminants, and disease to a person or cause infection if reused or used beyond a recommended period of time and more particularly to such an apparatus with a portion having a color changeable dye that changes color after being exposed to oxygen for a predetermined period of time indicating that the device should no longer be used.

The present application further relates to packaging for a product for human consumption wherein the product for human consumption can decline in freshness, quality of taste, and/or potency and/or can cause disease if consumed beyond a recommended period of time. More particularly the present application relates to such a packaging with a portion having a color changeable dye that changes color after being exposed to a predetermined percentage of oxygen for a predetermined period of time indicating that the product for human consumption should no longer be consumed or has decreased in freshness, quality of taste or potency.

BACKGROUND OF THE INVENTION

Many products currently marketed and sold to consumers are designed for limited use. These products are usually associated with a single event, a restricted time period or restricted access. There are many reasons for the need of single use or limited use products.

An example of a single use product is a disposable syringe. Instrument contamination and cross infection between patients is an ever present concern if the syringe is inadvertently reused. It is a particular concern in some countries where repeated use of instruments is known to transmit serious diseases such as HIV and hepatitis. Medical and ophthalmic devices that must be sterilized such as scalpels or tonometers (for the measurement of a patient's intraocular pressure) body piercing and tattooing instruments used on multiple clients also give cause for concern. Needles used in acupuncture offer another example. Decontamination procedures or employment of single-use devices are methods used to control cross infection, but they rely on personnel awareness, willingness to follow protocol, monitoring and documentation.

The limited use type of product is usually associated with goods that should be used for a restricted time period. One example of this type of product is "daily wear" or disposable contact lenses. Contact lenses for refractive correction or cosmetic purposes require suitable wear and care regimes in order to maintain good eye health. Non-compliance on the part of the patient, either through choice or due to lack of education, can injure the eye. Frequent replacement lenses are sometimes worn for longer than recommended or they may be stored or cleaned inappropriately.

A number of patents have tried to address the requirements for single use, limited use, or restricted access products.

U.S. Pat. No. 3,899,295 describes the use of an indicator containing a pH sensitive dye applied to the container of a product such as a medical instrument. The indicator displays a first color in a normal atmosphere, then following introduction of a basic atmosphere the sensor displays a second color. The problem with this patent is that the indicator is not displaying information relating to the condition of the product contained within the package. Since the indicator is not incorporated within or fixed onto the product, the information given actually relates to the container, not its contents. An additional problem with this patent is that the basic atmosphere in which the product is stored is chlorine gas which is highly reactive to the materials that comprise many of the products that one could imagine being supplied in a sterile package container, such as metal surgical instruments and many pharmaceutical compounds or drugs.

Similarly, U.S. Pat. No. 4,098,577 by the same inventor describes a similar pH sensitive indicator and two different atmospheric conditions, however that invention describes the indicator change in the presence of an acidic atmosphere. As described above, the indicator is not incorporated within or fixed onto the product, therefore the information presented by the indicator relates to the container, not its contents.

U.S. Pat. No. 4,526,752 presents a tamper resistant package with an indicator means. The invention describes a container which incorporates an indicator within its structure to display information on whether a container has been previously opened. As with other patents, the indicator relates to the condition of the package and not the product contained in the package.

U.S. Pat. No. 6,790,411 describes a solution based hydrogen peroxide indicator where the solution has a first color in normal atmospheric conditions, then following a sterilization process using hydrogen peroxide, the solution exhibits a second color. One will certainly recognize a problem with this technique by considering the case where a package that has been sterilized with hydrogen peroxide, is subsequently tampered with, punctured, or otherwise damaged and made non sterile, while the indicator still displays the sterile condition.

U.S. Pat. No. 6,851,808 describes an ophthalmic lens product with an attached indication means that provides the user information relating to the products condition or previous use. The invention overcomes many of the problems with the previously described patents. However, since the indicator means described in the patent uses changes in the product's light environment as the initiator for the use indication display, and since variations exist in the lighting

environment where the product is used, the use indication can present at a rate that is faster or slower than that which is optimally desired.

Many products currently marketed and sold to consumers are supplied prepackaged where the packaging is intended to preserve the freshness of the product or in the case of medication, the potency of the content within the packaging. These products are usually associated with a single event, i.e., the contents remain fresh or potent until the packaging is opened by the consumer.

An example of the importance of preservation of a packaged product is a cold tablet or a food item. Medicinal potency or food spoilage and the expense related to these issues are important to both consumers and manufacturers. Pharmaceuticals, food stuff, and similar items are commonly packaged in sealed plastic containers.

Atmospheric oxygen permeation through the plastic material of the container negatively affects the freshness of the contents of many packaged products. In the case of pharmaceuticals, oxygen absorption decreases potency. In the case of food products, oxygen absorption into the packaged food makes the food taste stale.

A number of patents have tried to address the requirements for packaging environment condition:

U.S. Pat. No. 4,285,697 describes the use of a spoilage indicator applied to the food within a container. The indicator displays a color indication in response to various gasses generated by the spoiled food. The indicator must be in contact with the product within the packaging. This patent does not describe a means to display the possible range of conditions about the packaged contents, such as good, acceptable or bad.

Similarly, U.S. Pat. No. 4,003,709 presents a method to indicate the deterioration of food within a package by detecting CO_2. This indicator does not have the possibility to indicate a range of freshness of the contents within the package.

U.S. Pat. No. 4,526,752 presents a tamper resistant package with an indicator means. The invention describes a container which incorporates an indicator within its structure to display information on whether a container has been previously opened. As with other patents, the indicator relates to whether the package has been opened or not, and not the condition of the unopened package and its contents.

U.S. Pat. No. 6,790,411 describes a solution based hydrogen peroxide indicator where the solution has a first color in normal atmospheric conditions, and then following a sterilization process using hydrogen peroxide, the solution exhibits another color. A package that has been sterilized with hydrogen peroxide, is subsequently tampered with, punctured, or otherwise damaged and made non sterile, would still display an indication of sterile conditions with this type of indicator.

U.S. Pat. No. 8,241,918 describes a freshness indicator for beverages using electronic data means and comparing the data via a processing unit to previously stored freshness criteria. This method is complex and expensive.

BRIEF SUMMARY OF THE INVENTION

In accordance with the present invention the disadvantages of prior limited use or restricted use products that can harm a person if improperly used as discussed above have been overcome. A disposable limited or restricted use apparatus in accordance with the present invention includes a color changeable portion wherein the time that the color change occurs is controlled so that it coincides to the approximate time of the end of one use of a single use apparatus or to the approximate expiration time for extended but limited or restricted use apparatus.

More particularly, the apparatus of the present invention with color change indication of use or expiration includes a limited or restricted use apparatus having a portion that comes in contact with bodily fluids or tissue so as to be susceptible to the transmission of contaminants or disease to a person or to cause infection or injury. A color changeable dye is disposed directly on a portion of the apparatus, the dye having a first color upon immediate exposure to oxygen and for a predetermined time thereafter and the dye changing color after the predetermined time to provide a warning indication that the apparatus should no longer be used.

In one embodiment of the present invention, the apparatus may be a medical device such as a disposable syringe wherein the predetermined period of time prior to color change is approximately five minutes. In another embodiment, the medical device is a disposable scalpel and the predetermined period of time before which the dye changes color is greater than or equal to one-half hour and preferably one hour. In still another embodiment, the apparatus is an ophthalmic device such as a disposable tonometer and the predetermined period of time before the color change occurs is approximately ten minutes.

In accordance with a further feature of the invention, the position of the dye on the device may be such that the device becomes unusable after the color change occurs.

In accordance with another feature of the present invention, the apparatus is a contact lens that is intended to be worn by a user such that the lens has a peripheral area that extends beyond the pupil and/or the iris of a user's eye when worn and wherein the contact lens is disposable such that it is not intended to be used for more than a predetermined period of time. A color changeable dye is disposed on a portion of the peripheral area of the contact lens wherein the dye is somewhat translucent prior to use of the contact lens and the dye changes to a visible color after the contact lens has been exposed to oxygen for a predetermined period of time indicating that the contact lens should no longer be used. Because the color change indication of expiration is in the periphery of the lens, it does not obstruct the optical zone of the lens. As such, the lens can still be used without obstructing vision after the color change occurs. However, a user is discouraged from continuing to wear the expired contact lens since the color change indication is visible and apparent to others.

An apparatus including a disposable limited or restricted use product in accordance with the present invention includes an oxygen sensing color changeable dye disposed on a portion of the apparatus, the dye being translucent or having a first color upon application and for a defined time thereafter and the dye changing color after exposure to oxygen for the defined time.

The dye can comprise and indicator such as Methylene Blue or Safranine T. The dye can also include glucose, sodium hydroxide, Iron (II) carbonate, wax, methyl cellulose and/or acacia gum.

The dye can be printed on the restricted or limited use product. The restricted or limited use product can be a medical device such as a scalpel, a syringe, or an ophthalmic lens. In another embodiment the dye is disposed upon a product for human consumption such as a pill.

The apparatus can also be a packaging for a product for human consumption. The dye disposed on a portion of the

packaging. For example, the dye can be disposed on an interior of the packaging so that it is visible from an exterior of the packaging.

The product for human consumption can decrease in freshness, quality of taste or potency after exposure to oxygen for a period of time. The defined time after which the dye changes color can be coordinated to be approximately equal to the period of time after which the product for human consumption decreases in freshness, quality of taste or potency in order to indicate freshness, quality of taste and potency to a potential purchaser.

The packaging can have a second oxygen sensing color changeable dye disposed on it, the dye being translucent or having a first color upon application and for a second defined time thereafter and the dye changing color after exposure to a second defined percentage of oxygen for the second defined time. The packaging can further have at least one other oxygen sensing color changeable dye disposed on it, the dye being translucent or having a first color upon application and for at least one other defined time thereafter and the dye changing color after exposure to at least one other defined percentage of oxygen for the at least one other defined time.

In one embodiment of the packaging with at least three dyes thereon, the first dye changes color after exposure to approximately 5% oxygen for approximately 1 minute, said second dye changes color after exposure to approximately 10 to 15% oxygen for approximately 1 minute and said other dye changes color after exposure to approximately 20% oxygen for approximately 1 minute. In another embodiment of the packaging with at least three dyes thereon, the first dye changes color after exposure to approximately 5% oxygen for approximately 1 minute, said second dye changes color after exposure to approximately 10 to 15% oxygen for approximately 10 minutes and said other dye changes color after exposure to approximately 20% oxygen for approximately 1 hour. In yet another embodiment of the packaging with at least three dyes thereon, the first dye changes color after exposure to approximately 5% oxygen for approximately 10 minutes, said second dye changes color after exposure to approximately 10 to 15% oxygen for approximately 10 minutes and said other dye changes color after exposure to approximately 20% oxygen for approximately 10 minutes. In yet another embodiment of the packaging with at least three dyes thereon, the first dye changes color after exposure to approximately 5% oxygen for approximately 1 hour, said second dye changes color after exposure to approximately 10 to 15% oxygen for approximately 10 minutes and said other dye changes color after exposure to approximately 20% oxygen for approximately 1 minute.

The product for human consumption inside the packaging can also have an oxygen sensing color changeable dye disposed thereon, the dye being translucent or having a first color upon application and for a defined time thereafter and the dye changing color after exposure to atmospheric oxygen for the defined time.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

FIG. **1** is a perspective view of a syringe in accordance with one embodiment of the present invention depicting the area of the color changeable dye overlying the graduated scale of the syringe;

FIG. **2** is a perspective view of the syringe of FIG. **1** depicting the syringe after the timed color change occurs;

FIG. **3** is an illustration of an alternative placement of the dye on a syringe;

FIG. **4** is an illustration of the syringe of FIG. **3** with an expiration message printed with the color changeable dye which becomes visible after a predetermined period of time;

FIG. **5** is a perspective view of the syringe of FIG. **3** contained in a package to prevent premature actuation of the color changeable dye;

FIG. **6** is a perspective view of a scalpel with the color changeable dye in accordance with another embodiment of the present invention;

FIG. **7** is a perspective view of the scalpel of FIG. **6** with a message printed with the color changeable dye which has become visible after a predetermined time;

FIG. **8** is a cross-sectional view of a tonometer contacting a user's eye and having the color changeable dye disposed on a central area of the tonometer lens through which the clinician looks;

FIG. **9** is a cross-sectional view of the tonometer and eye of FIG. **8** with the dye providing a color change indication that the tonometer should no longer be used;

FIG. **10** is a cross-sectional view of a contact lens in accordance with another embodiment of the present invention on a user's eye;

FIG. **11** is a front perspective view of the contact lens of FIG. **10** with the dye in peripheral areas of the contact lens;

FIG. **12** is a front perspective view of the contact lens of FIG. **11** depicting the dye after color change has occurred to indicate expiration of the lens;

FIG. **13** is an alternative embodiment of the contact lens of FIG. **11**; and

FIG. **14** is a cross-sectional view of a package containing the contact lens of FIG. **11** to prevent premature color change.

FIG. **15** is a perspective view of a packaging in accordance with one embodiment of the present application depicting the area of the sequential color changeable printed inside the packaging and observable through the closed packaging.

FIG. **16** is an illustration of an oxygen indicator scale showing the freshness information of the inside of a closed packaging.

FIG. **17** is an illustration of a packaging of FIG. **1** depicting the packaging and indicator scale after the first in the series of color change occurs.

FIG. **18** is an illustration of a packaging of FIG. **1** depicting the packaging after the last in the series of color change occurs.

FIG. **19** is an illustration series showing the multi-step printing of the indication in text while the previous text message is blanked out by the newly activated indicator.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, a color change indication on a product provides accurate information or a warning to a user of: prior use of a single use product or instrument; a reminder that a limited use product has reached it's expiration time; or that a product that is restricted for use has been tampered with. The warning indication is provided by a dye that changes color in a time controlled manner wherein the dye is disposed on the product itself by being either printed on the product or incorporated within the material forming a portion of the product. The product is then subsequently packaged to provide a sterile environment for the product or limited

access thereto. The internal atmosphere of the package is an inert gas or a vacuum such that the package provides a sealed, substantially atmospheric oxygen free environment for the product. When the package is subsequently opened and the product is exposed to atmospheric oxygen, the dye disposed on the product will change from translucent or somewhat translucent, i.e. a milky white or "water white," to a blue or red color after a period of time that is controlled by the composition of the dye as discussed in detail below, and that is selected to correspond to the typical time for a single use of a product in the case of single use products or that corresponds to the expiration time of the product. The time at which the dye changes color can also be selected so as to indicate that the product may have been tampered with.

In accordance with one embodiment of the present invention, as shown in FIG. **1**, a disposable syringe **10** includes a graduated scale **12** printed thereon so that the amount of liquid drawn into the syringe can be accurately measured. In one embodiment, the color changeable dye **14** is printed over the scale. In this embodiment, the dye is substantially translucent so that the scale is clearly visible until the dye **14** changes color, as depicted at **14'** in FIG. **2**, after a predetermined time associated with the time of typical use of the single use disposable syringe **10**.

For single use disposable products where the dye is required to be substantially translucent and wherein the dye is to change color after exposure to oxygen after five to ten minutes, the dye solution may be formed as follows. Approximately 12 grams of glucose is added to 600 cc of distilled de-ionized water. Next, approximately 12 grams of sodium hydroxide is added to the mixture. To this mixture is added 10 cc of a Methylene Blue solution prepared by mixing 0.1 gram of Methylene Blue in 100 cc of ethanol where the ethanol evaporates in the drying process. Thereafter, 60 grams of methyl cellulose is added to the mixture. Alternatively, E414 acacia gum may be substituted for the methyl cellulose. This dye solution will change from translucent to blue in a short amount of time after the package is opened and the product on which the dye is disposed is exposed to oxygen. If the color change desired is from substantially translucent to a red color, 10 cc of a Safranine T solution can be substituted for the Methylene Blue solution. The Safranine T solution is prepared by mixing 0.3 grams of Safranine T with 10 ml of ethanol.

In order to delay the time at which the dye changes color upon exposure to oxygen, Iron (II) carbonate can be added to the above dye solution. For example, 0.1 grams of Iron (II) carbonate can be added to a 3 ml quantity of the above dye solution forms a dye that will change color to either blue or red after approximately nine or ten minutes. By increasing or decreasing the amount of Iron (II) carbonate the time that it takes for the color change to occur upon exposure to oxygen can be respectively increased or decreased. It is noted that, the addition of the Iron (II) carbonate will change the dye from being substantially translucent to somewhat translucent or a faint, milky white known as "water white" wherein the translucency diminishes as more Iron (II) carbonate is added.

In a preferred embodiment of the disposable syringe, a dye is employed that remains translucent or somewhat translucent for a period of approximately five minutes, the typical time of a single use of the disposable syringe. In the embodiment of the syringe depicted in FIGS. **1** and **2**, because the dye is disposed over the graduated scale, when the time controlled color change occurs, the graduated scale is no longer clearly visible so that the disposable syringe cannot be accidentally reused. In this manner, the transmission of contaminants or disease from one patient to another by an inadvertent reuse of the syringe is prevented.

In another embodiment of the present invention as depicted in FIGS. **3** and **4**, the dye is disposed on another area such as **18** of the disposable syringe **10**. The dye can be used as an ink to print a message on the disposable product so that when the color change occurs the message, such as the word "USED," becomes visible to the user as shown at **18'** in FIG. **4**. The dye of the present invention dries quickly after placed on the product. After it is dry, the product can be sterilized with any common, low temperature sterilization technique and then placed in a sealed container or package **16**, as depicted in FIG. **5**, with an internal atmosphere of an inert gas or a vacuum. In the sealed, substantially atmospheric oxygen free package, the ink will remain translucent or "water white". When the package is subsequently opened and the product is exposed to atmospheric oxygen, the dye disposed on the product will change from substantially translucent or "water white" to blue or red after five or ten minutes depending upon the amount of Iron (II) carbonate in the solution.

If it is desired that the color change takes substantially longer than ten minutes, for example, twelve to sixteen hours, 0.5 grams of Iron (II) carbonate is added to a 3 ml quantity of the dye solution instead of 0.1 grams of Iron (II) carbonate. It is noted that the Iron (II) carbonate acts as an oxygen scavenger in the dye solution that preferentially absorbs oxygen, converting to Iron (III) carbonate. When the Iron (II) carbonate is completely converted to Iron (III) carbonate, the oxygen in the environment reacts with the color changeable dye so that the dye changes to blue or red and becomes visible.

In order to prevent the dye from changing color until an even longer time has passed, wax can be added to the dye solution. To provide a color change indication on a product after approximately 1500 hours or about two months, the oxygen diffusion rate through the dye solution can be lowered or decreased by the addition of wax as follows. Specifically, when 0.3 cc of beeswax is added to a 3 ml quantity of the dye described above, the color change is delayed by approximately ten hours for a volume of dye of 0.01 mm3. This amount of dye can be used in an area of approximately 2 mm in height and 20 mm long on a product. With the addition of 0.6 cc beeswax to the dye solution, the color change can be delayed to approximately 100 hours. To further extend the time that it takes for the color change to 1500 hours, 0.7 grams of Iron (II) carbonate can be added to the dye solution and wax mixture. It is noted that if too much wax is added to the dye, the quality of printing text can decrease.

In another embodiment of the present invention as depicted in FIG. **6**, a disposable scalpel **24** has the dye **26** of the present invention disposed thereon in an area that will be clearly visible to the surgeon when the dye changes color. As depicted in FIG. **7**, a warning message **28** may be printed with the dye on the scalpel to inform the surgeon that the scalpel has been "USED" wherein the color change occurs after at least one-half hour and preferably one hour after the scalpel is removed from a substantially oxygen free package or container as discussed above with respect to the syringe. In this way, the surgeon is warned that the scalpel should not be inadvertently used again but should be disposed of.

An ophthalmic device that incorporates the present invention is depicted in FIGS. **8** and **9**. Specifically, FIG. **8** illustrates a tonometer **29** that is used in contact with a patient's eyes **30**. In ophthalmology, various procedures require a lens or instrument that contacts a patient's eye. A

tonometer is one such device which includes a lens **31** which, for a disposable tonometer, may be formed of optical quality acrylic, for example. The lens **31** has a surface **33** through which a clinician views the eye **30** when the tonometer **29** is mounted on a slit lamp. The tonometer **29** also includes a holder **29** which is used to mount the tonometer onto the slit lamp. For a disposable tonometer, the holder **29** can be formed of plastic for example. In accordance with one embodiment, the dye **32** of the present invention can be disposed on a central area of the lens **31** of the tonometer. Since the typical time of use of the disposable tonometer **29** of the present invention is very short, the dye **32** can be of a formulation that is substantially translucent and does not change color for approximately five to ten minutes. After that time, when the dye changes color to blue or red, the dye prevents inadvertent reuse of the disposable tonometer by blocking the visual path in the tonometer to the patient's eye. Thus, the inadvertent transmission of contaminants or diseases from one patient to another patient via contact of a reused ophthalmic device with the patient's eyes is prevented. In another embodiment of the present invention, the dye can be disposed to form a ring or other symbol on the surface **33** of the tonometer lens **31** or the dye can be disposed on the holder of the tonometer **36**.

A problem that has arisen in ophthalmology with refractive contact lens use such as "daily wear" or "monthly wear" disposable contact lenses is that the user of the contact lens does not dispose of the contact lens at the recommended time but wears the contact lens longer than they are supposed to. This however can damage the eye. The contact lens of the present invention as depicted in FIGS. **10-14** overcomes this problem by providing a visual indication on the contact lens itself that the contact lens should be removed from the eye after the contact lens has been worn for the prescribed amount of time.

As shown in FIG. **10**, a refractive contact lens **40** is worn on a cornea **36** of an eye **30**. Light **44** entering the person's cornea is correctly focused by the contact lens **13** onto the retina at a point **45**. The clear optical path of the light **44** intersects the central portion of the contact lens in the optical zone **48** of the eye and or lens. The periphery **43** of the contact lens **40** as shown in FIGS. **10-13**, however extends beyond the optical zone **48** of the user's eye such that when the contact lens is worn, the peripheral area of the contact lens extends beyond the pupil and/or iris of a user's eye so that it overlies the iris and/or the sclera.

In accordance with the present invention, the color changeable dye **46** as described above is disposed on a portion of the peripheral area of the contact lens. The formulation for the dye is preferably that which delays the color change of the dye for approximately twelve to sixteen hours, or longer, according to the longest time that the contact lens manufacturer suggests that the contact lenses should be worn. Because the formulation for the dye for twelve to sixteen hours includes Iron (II) carbonate, prior to the color change, the dye is milky white or "water white". However, when the dye is disposed in one or more areas such as **46** and **47** in the periphery **43** of the contact lens **40**, when the contact lens is worn by the user the area in which the dye is placed on the contact lens overlies the iris and/or the sclera and is not visible to an observer. As discussed above for the other devices, the contact lens **40** should be placed in a substantially atmospheric oxygen free package **50** as shown in FIG. **14**. A user of the contact lens **40** removes the contact lens from the package for immediate use in the eye. After the contact lens has been worn in the eye for the recommended time by the manufacturer, the color change of the dye occurs as depicted in FIG. **12** wherein, dark blue or dark red spots are clearly visible in the periphery of the contact lens by an observer looking into the contact lens wearer's eye. As such, the contact lens wearer is encouraged to remove the contact lens from his eye and dispose of it as recommended. However, because the dye is disposed in the periphery of the contact lens outside of the optical zone **48**, the dye, after it changes color does not impair the vision of the user. As such, in emergencies, the contact lens can be continued to be worn after the color change occurs without visual impairment. However, the user is discouraged from wearing the lens beyond its recommended use time since the die spots or ring will be readily apparent by anyone looking at the contact lens wearer's eye.

FIG. **13** illustrates another embodiment of the positioning of the dye to form portions of a ring or a continuous ring in the periphery **43** of the contact lens outside the optical zone **48**.

In accordance with another embodiment of the present invention, a color change indication on a packaging provides accurate information or a warning to a user: that a product for human consumption within the packaging has reached its expiration time; that a product for human consumption has decreased in freshness, quality of taste or potency or that a product for human consumption within the packaging has been tampered with. The warning indication is provided by a dye that changes color in a time controlled manner wherein the dye is disposed on the packaging by being either printed on the packaging or incorporated within the material forming a portion of the packaging. The dye is safe for human consumption so that it can come into contact with the product for human consumption without any health concerns. In an alternative embodiment, the dye could be printed on the product for human consumption itself without any health concerns.

The dye can be disposed on the interior of the packaging while also being visible from the exterior of the packaging. Disposing the dye on the interior of the packaging allows the color changing dye to monitor the environment inside the packaging where the product for human consumption is contained. Making the dye visible from the exterior of the packaging allows the user to determine the environment on the interior of the packaging where the product for human consumption is contained without opening the packaging. For example, a packaging of the present application could contain a food product on the interior of the packaging. A portion of the food packaging could be a clear material with the color changeable dye located on the interior of the clear portion. The color changeable dye could then be viewed by the user from the exterior while measuring the environment on the interior with the food product. FIG. **15** is a perspective view of a packaging in accordance with one embodiment of the present invention depicting the area of the color changeable dye printed inside the packaging and observable through the closed packaging.

The product for human consumption is packaged into the packaging of the present application to provide a sterile environment for the product and/or limited access thereto. The internal environment of the unopened packaging has a certain percentage of oxygen (O_2) present. For example the internal environment of the unopened packaging could be the same as the atmosphere which contains approximately 21% oxygen. Alternatively, the packaging could be "flood packaged" by pumping in other gases, e.g. carbon dioxide or inert gases, during packaging. A packaging that was flood packaged would have an internal environment with less than 21% oxygen. For example, a flood packaged internal envi-

ronment could contain 15-20% oxygen, 10-15% oxygen, 5-10% oxygen or 1-5% oxygen. In another example, the packaging could by packaged in a vacuum such that the packaging provides an internal environment that is substantially oxygen free or approximately 0% oxygen. When the flood packaging or vacuum packaging is subsequently opened, the internal environment and the product for human consumption therein are exposed to atmospheric oxygen and the oxygen percentage will increase.

After the product for human consumption is exposed to a certain percentage of oxygen for a certain period of time, the product for human consumption may reach its expiration or decrease in freshness, quality of taste or potency of the product. The length of the period of time after which a product for human consumption reaches its expiration or decreases in freshness, quality of taste, or potency varies depending on the percentage of oxygen in the environment to which the product for human consumption is exposed. For example, a food product will reach its expiration or decreases in freshness or quality of taste more slowly in a closed packaging at 10% oxygen than in an open packaging at 21% oxygen. These specific times and oxygen levels are only an example and would differ depending on the internal product. For example, coffee that is exposed to oxygen decreases in freshness and quality of taste very quickly whereas potato chips decrease in freshness and quality of taste more slowly.

After the dye has been exposed to a certain percentage of oxygen for a certain period of time, the dye disposed on the packaging will change from translucent or somewhat translucent, i.e. a milky white or "water white," to a blue or red color after a period of time that is controlled by the composition of the dye as discussed in detail below. The time after which the dye changes color is selected to correspond to the length of the period of time after which a product for human consumption reaches its expiration or decreases in freshness, quality of taste, or potency at a certain percentage of oxygen. For example, if a food product is stored in a packaging with 10% oxygen and is known to expire or lose freshness or quality of taste after exposure to 10% oxygen for two weeks, the dye could be timed to change color after exposure to the 10% oxygen environment for two weeks. A potential purchaser of the product could then see that the food was expired or lower in freshness or quality of taste by looking at the colored dye. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product.

A dye will change at a different time when exposed to a different percentage of oxygen. This feature of the dye allows them to also be used to monitor the internal environment of the closed packaging. For example, a vacuum packed bag of coffee might maintain freshness and quality of taste in a substantially oxygen free environment for two weeks but will lose freshness and quality of taste in a 10% oxygen environment within a week and in a 21% oxygen environment within a day. This could be used with a dye that take two weeks to change in an oxygen free environment but only 1 week in a 10% oxygen environment and only 1 day in a 21% oxygen environment. If the vacuum packaging is compromised and the oxygen environment within the packaging changes, the dye would change indicating the potential effect on the coffee to the potential purchaser. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product.

Different compositions of dye can be disposed on the packaging in a sequential arrangement so the dye changes at different times to indicate a freshness or potency level as the freshness, quality of taste or potency changes. FIG. **16** is an illustration of an oxygen indicator scale showing the freshness, quality of taste or potency information of the product inside of the closed packaging. The oxygen indicator scale has different compositions of dye at the end of the scale that indicates "good" and the level that indicates "bad." The dyes will change at different times as the product's freshness, quality of taste or potency goes from good to bad. FIG. **17** is an illustration of a disposable packaging apparatus of FIG. **16** depicting the packaging and indicator scale after the first in the series of color change occurs. FIG. **18** is an illustration of a disposable packaging apparatus of FIG. **16** depicting the packaging after the last in the series of color change occurs.

As an example of the sequential indicator, a food product could begin to decline in freshness or quality of taste after two weeks in an internal environment of 10% oxygen and continue the decline in an internal environment of 10% oxygen until its expiration date at one month. The dye at the "good" end of the scale could turn after two weeks, the dye at the middle end of the scale could turn at three weeks and the dye at the "bad" end of scale could turn at one month. This would indicate the level of freshness to the potential purchaser before they purchase and open the product. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product. Other words or symbols could be used in this indicator scheme and more levels of indication could be added.

In yet another embodiment of the invention the sequential dye indicators are printed on top of each other, and given that the indicator dye is relatively transparent until activated, the dyes may be printed such that a text message appears indicating the conditions within the packaging and that the previous message is blacked out by the newly activated indicator in the sequence. FIG. **19** is an illustration series showing the multi-step printing of the indication in text while the previous text message is blanked out by the newly activated indicator.

As an example of this sequential indicator, a food product could begin to decline in freshness or quality of taste after two weeks in an internal environment of 10% oxygen and continue the decline in an internal environment of 10% oxygen until its expiration date at one month. In this example, the term "good" could been written in a first dye that changes almost immediately after the food product is placed in the packaging at 10% oxygen or in a non-changing dye in the same color as the indicating color of the color changing dye. A second dye which changes color after two weeks at 10% oxygen could be applied over the "good" indicator to black it out and the term "ok" could be written in the next area of the scale in that same dye. Finally, a third dye which changes color after four weeks at 10% oxygen could be applied over the "ok" indicator to black it out and the term "bad" could be written in the next area of the scale in the same dye. In this example, the potential purchaser would see the "good" indicator for the first two weeks when the product is freshest. That indicator would be blacked out after those two weeks and the potential purchaser would see the "ok" indicator during the two weeks after that when the product is starting to decline in freshness but has not yet expired. That indicator would be blacked out after four weeks and the potential purchaser would see the "bad" indicator. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product. Other words or symbols could be used in this indicator scheme and more levels of indication could be added.

The prior examples use a constant percentage of oxygen with the sequential indicators. However, the sequential indicators can also be used to monitor varying oxygen levels. For example, a product could decrease in freshness or quality of taste after exposure to 5% oxygen after 1 minute, 10% oxygen after 1 minute and greater than 15% oxygen after 1 minute. The product could be vacuum packaged to be substantially free of oxygen. Dyes that change after exposure to 5% oxygen after 1 minute, 10% oxygen after 1 minute and 20% oxygen after 1 minute could be used as the three dyes on the sequential indicator. If the environment in the package reaches 5% oxygen the first dye will change after 1 minute. If the environment in the package reaches approximately 10% oxygen the second dye will change after 1 minute. If the environment in the package reaches 20% oxygen the third dye will change after 1 minute. Alternatively, these changes could each occur after 10 minutes. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product. Other words or symbols could be used in this indicator scheme and more levels of indication could be added.

As yet another example, a product could decrease in freshness or quality of taste after exposure to 5% oxygen after 1 minute, 10 to 15% oxygen after 10 minutes and 20% oxygen after 1 hour. The product could be vacuum packaged to be substantially free of oxygen. Dyes that change after exposure to 5% oxygen after 1 minute, 10 to 15% oxygen after 10 minutes and 20% oxygen after 1 hour could be used as the three dyes on the sequential indicator. If the environment in the package reaches 5% oxygen the first dye will change after a minute. If the environment in the package reaches 10 to 15% oxygen the second dye will change after 10 minutes. If the environment in the package reaches 20% oxygen the third dye will change after one hour. As yet another example, a product could decrease in freshness or quality of taste after exposure to 5% oxygen after 1 hour, 10 to 15% oxygen after 10 minutes and 20% oxygen after 1 minute. The product could be vacuum packaged to be substantially free of oxygen. Dyes that change after exposure to 5% oxygen after 1 hour, 10 to 15% oxygen after 10 minutes and 20% oxygen after 1 minute could be used as the three dyes on the sequential indicator. If the environment in the package reaches 5% oxygen the first dye will change after an hour. If the environment in the package reaches 10 to 15% oxygen the second dye will change after 10 minutes. If the environment in the package reaches 20% oxygen the third dye will change after one minute. These specific times and oxygen levels are only an example and could be changed to correspond to the internal product. Other words or symbols could be used in this indicator scheme and more levels of indication could be added.

For applications where the dye is required to be substantially translucent and wherein the dye is to change color after exposure to 21% oxygen after approximately 5-10 minutes, the dye solution may be formed as follows. Approximately 12 grams of glucose is added to 600 cc of distilled deionized water. Next, approximately 12 grams of sodium hydroxide is added to the mixture. To this mixture is added 10 cc of a Methylene Blue solution prepared by mixing 0.1 gram of Methylene Blue in 100 cc of ethanol where the ethanol evaporates in the drying process. Thereafter, 60 grams of methyl cellulose is added to the mixture. Alternatively, E414 acacia gum may be substituted for the methyl cellulose. This dye solution will change from translucent to blue in a short amount of time after the packaging is opened and the product on which the dye is disposed is exposed to oxygen. If the color change desired is from substantially translucent to a red color, 10 cc of a Safranine T solution can be substituted for the Methylene Blue solution. The Safranine T solution is prepared by mixing 0.3 grams of Safranine T with 10 ml of ethanol.

In order to delay the time at which the dye changes color upon exposure to oxygen, Iron (II) carbonate can be added to the above dye solution. For example, 0.1 grams of Iron (II) carbonate can be added to a 3 ml quantity of the above dye solution forms a dye that will change color to either blue or red after approximately 9-10 minutes of exposure to 21% oxygen. By increasing or decreasing the amount of Iron (II) carbonate the time that it takes for the color change to occur upon exposure to oxygen can be respectively increased or decreased. It is noted that, the addition of the Iron (II) carbonate will change the dye from being substantially translucent to somewhat translucent or a faint, milky white known as "water white" wherein the translucency diminishes as more Iron (II) carbonate is added.

If it is desired that the color change takes substantially longer than 10 minutes at 21% oxygen, for example, 12-16 hours at 21% oxygen, 0.5 grams of Iron (II) carbonate is added to a 3 ml quantity of the dye solution instead of 0.1 grams of Iron (II) carbonate. It is noted that the Iron (II) carbonate acts as an oxygen scavenger in the dye solution that preferentially absorbs oxygen, converting to Iron (III) carbonate. When the Iron (II) carbonate is completely converted to Iron (III) carbonate, the oxygen in the environment reacts with the color changeable dye so that the dye changes to blue or red and becomes visible.

In order to prevent the dye from changing color until an even longer time has passed, wax can be added to the dye solution. To provide a color change indication on a product after approximately 1500 hours at 21% oxygen, the oxygen diffusion rate through the dye solution can be lowered or decreased by the addition of wax as follows. Specifically, when 0.3 cc of beeswax is added to a 3 ml quantity of the dye described above, the color change is delayed by approximately ten hours at 21% oxygen for a volume of dye of 0.01 mm3. This amount of dye can be used in an area of approximately 2 mm in height and 20 mm long on a product. With the addition of 0.6 cc beeswax to the dye solution, the color change can be delayed to approximately 100 hours at 21% oxygen. To further extend the time that it takes for the color change to approximately 1500 hours at 21% oxygen, 0.7 grams of Iron (II) carbonate can be added to the dye solution and wax mixture. It is noted that if too much wax is added to the dye, the quality of printing text can decrease.

A person familiar with the present technology could calculate the time at which the dyes discussed herein would change in the presence of a different percentage of oxygen.

The present invention has much wider applications than have been described herein. For example, the dye of the present invention can be used on cosmetic applicators that are stored with the cosmetic itself such as mascara or eyeliner. It has been found that although such cosmetics include preservatives to slow the growth of bacteria that can infect the eye, these preservatives have a limited life so that replacement of cosmetics is recommended by doctors every three to six months. The cosmetics however do not have an expiration date on the product or the package. The dye of the present invention can be applied to the handle of a mascara applicator or eyeliner applicator, for example, so that a warning message becomes visible at the recommended time of replacement. As such a user is warned that the cosmetic should be disposed of prior to the expiration of the preservative to prevent eye infections. The present invention is also applicable to oral medications such as pills wherein the

dye is printed directly onto the pill and changes color from white or translucent to another darker color or warning symbol when the environmental oxygen level around the pill changes. If the pills are individually packaged, the color change indication can occur quickly after opening the package so as to provide a tamper indication. As another example, in markets where counterfeit pills are a problem the color changeable dyes of the present invention could be applied to the real pills. After exposure to atmospheric oxygen for a predetermined period of time, the real pills would change color but counterfeits would not. Instructions could be included indicating that pills that do not change after exposure to atmospheric oxygen for a predetermined period of time should not be used. Alternatively, if multiple pills are contained in a bottle or the like, the color change indication of the dye should be timed to coincide with the expiration of the pills. It is noted that in preparing the, Methylene Blue solution, instead of ethanol, another type of alcohol can be used wherein the alcohol evaporates on the pill in the drying process.

Many further modifications and variations of the present invention are possible in light of the above teachings. Thus, it is to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as described hereinabove.

The invention claimed is:

1. An apparatus with controlled color change indication comprising:

a packaging comprising a disposable, limited or restricted use product;

an oxygen sensing color changeable dye disposed within the packaging, the dye being translucent or having a first color upon application and the dye changing color after exposure to less than atmospheric levels of oxygen of approximately 5 to 15% oxygen within the packaging

wherein the dye indicates the condition of the disposable, limited or restricted use product.

2. An apparatus as recited in claim **1** wherein the disposable, limited or restricted use product decreases in freshness, quality or potency after exposure to the less than atmospheric oxygen for a defined period of time.

3. An apparatus as recited in claim **2** wherein the defined time after which the dye changes color is approximately equal to the period of time after which the disposable, limited or restricted use product decreases in freshness, quality or potency.

4. An apparatus as recited in claim **1** wherein the dye is printed on the disposable, limited or restricted use product.

5. An apparatus as recited in claim **1** wherein said apparatus is a packaging for a product for human consumption.

6. An apparatus of claim **1** wherein the dye is disposed on a portion of the packaging.

7. A packaging as recited in claim **1** wherein the dye is disposed on an interior of the packaging and is visible from an exterior of the packaging.

8. An apparatus as recited in claim **5** wherein the product for human consumption decreases in freshness, quality of taste or potency after exposure to the percentage of oxygen for a period of time.

9. An apparatus as recited in claim **8** wherein the defined time after which the dye changes color is approximately equal to the period of time after which the product for human consumption decreases in freshness, quality of taste or potency.

10. An apparatus as recited in claim **1** wherein said dye is disposed upon a product for human consumption.

11. An apparatus as recited in claim **10** wherein said product for human consumption is a pill.

12. An apparatus as recited in claim **10** wherein the product for human consumption decreases in freshness, quality of taste or potency after exposure to the percentage of oxygen for a period of time.

13. An apparatus as recited in claim **12** wherein the defined time after which the dye changes color is approximately equal to the period of time after which the product for human consumption decreases in freshness, quality of taste or potency.

14. An apparatus as recited in claim **1** wherein said dye is further configured to change color at a defined time.

15. An apparatus as recited in claim **14** wherein the defined time is approximately equal to the expiration of the product.

16. An apparatus as recited in claim **1** wherein the apparatus further comprises a second oxygen sensing color changeable dye disposed within the packaging wherein the second dye is configured to change color after exposure to a second defined percentage of oxygen within the packaging.

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