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Via Email: dsefcik@nist.gov
And U.S. Mail

Mr. David A. Sefcik
NIST, Weights and Measures
100 Bureau Drive - M/S 2600
Gaithersburg MD 20899-2600

Dear Mr. Sefcik:

It was a pleasure to speak with you by telephone on March 30, 2011 to discuss the questions and comments raised in your email letter regarding the quantity designation on the label for the PURE CITRUS non-aerosol room spray product.

FDA Regulations

During our conversation, I mentioned that the FDA had in its regulations for packaging and labeling, an exception for foods packed in containers designed to deliver the food under pressure. I was able to locate the exact FDA regulation that is found in the FDA Manual Guide, 7563.7, in the regulation designated 21 CFR 101.105(g) reading as follows:

[i]n the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration. [net quantity is defined in 21 CFR 101.105(a) as "fluid measure if the food is liquid]

Other Pressurized Spray Products Labeled in Fluid Ounces

Also, during our conversation, we discussed that other manufacturers using the new BOV technology include fluid ounces as the label designation. Specifically, the manufacturer of Coppertone uses BOV technology in its SPORT Sunscreen product and labels its package in 6 fluid ounces. Likewise, the manufacturer of SIMPLY SALINE for Wound Wash Saline uses BOV technology in its product and labels its package as 3.0 fluid ounces.

NIST Guidelines

The above FDA exception for foods in pressurized containers is inconsistent with the guidelines section of NIST Handbook 130 , Sections 6.4 and 10.3 when read together:

“6.4. Terms: Weight, Measure, Volume, or Count. – The declaration of the quantity of a particular commodity shall be expressed in terms of:

- (a) weight if the commodity is solid, semisolid, viscous, or a mixture of solid and liquid; or
- (b) volume measure if the commodity is liquid or dry, if the commodity is dry; or
- (c) linear measure or area; or
- (d) numerical count.

However, if there exists a firmly established general consumer usage and trade custom with respect to the terms used in expressing a declaration of quantity of a particular commodity, such a declaration of quantity may be expressed in its traditional terms, provided such traditional declaration gives accurate and adequate information as to the quantity of the commodity. Any net content statement that does not permit price and quantity comparisons is forbidden.”

“10.3. Aerosols and Similar Pressurized Containers. The declaration of quantity on an aerosol package and on a similar pressured shall disclose the net quantity of the commodity (including propellant), in terms of weight, that will be expelled when instructions for use as shown on the can.”

Currently the NIST is interpreting the requirement in Section 6.4 that the declaration of quantity be a volume measurement if the commodity is a liquid like air freshener as being overridden by the provision in 6.4 that net weight may be used since net weight is “a firmly established general consumer usage and trade custom”

Unfortunately, NIST’s interpretation of the requirements of Section 6.4 to permit labeling of air freshener by net weight overlooks the most important part of Section 6.4:

Any net content statement that does not permit price and quantity comparisons is forbidden.

For conventional aerosol air sprays like Glade, “the firmly established general consumer usage and trade customer” that permits a declaration of net weight does not permit price and quantity comparisons without a requirement to declare the weight or volume of **active** ingredients expelled.

- The net weight declaration deceives the consumer into believing that the active ingredients expelled are the net weight.
- In fact, the active ingredients are not listed on the package.
- What is expelled includes mostly water, and propellant.

- Only a small quantity of active ingredients are expelled (perhaps 5% or less).
- The consumer expects to buy fragrance and odor-reducing active ingredients that are expelled.
- The consumer is not expecting to buy water and propellant that is the majority of the contents expelled.
- NIST guidelines do not require the declaration of the weight or volume of active ingredients.
- The consumer cannot compare the weight or volume of active ingredients expelled.
- The “commodity” referred to in Sec. 6.2 is only the active ingredient.
- The weight or volume of “active ingredients” are what the consumer needs to compare from one product to another.

Since the NIST guidelines do not currently require a declaration of the weight or volume of **active** ingredients expelled, the consumer cannot make price and quantity comparisons required by the guidelines for different mixtures of active ingredients. For example, one manufacturer of aerosols can mix 5% active ingredients of fragrance and another manufacturer can mix 10% and each charge the same price, yet the consumer cannot make a price and quantity comparison of the commodity (fragrance) for which the consumer is purchasing the product.

PURE CITRUS currently shows on its can the volume of its active ingredients expelled in fluid measurement. PURE CITRUS is actually more in compliance with the guidelines than the conventional aerosol manufacturers. **PURE CITRUS reveals the active ingredients (100%), the quantity, and the price.**

There are two solutions to the serious violation of the guideline against “*Any net content statement that does not permit price and quantity comparisons is forbidden*”:

1. NIST can amend Sections 6.2 and 10 to require adding to the declaration of net weight the weight or volume of active ingredients expelled, or
2. NIST can amend Sections 6.2 and 10 to require air sprays to declare only the active ingredient expelled in terms of weight or volume

Until NIST makes one of these changes to its guidelines, the maker of PURE CITRUS requests that NIST consider the new BOV Technology as not within the scope of a conventional aerosol package or a “similar pressurized package” for which the current NIST guidelines were apparently drafted and have been applied. Alternatively, the makers of PURE CITRUS requests a waiver of compliance with the current guidelines.

Reponses to Questions Raised in Your Letter

In answer to your questions raised in your email letter of March 1, 2011, please consider the responses below:

1. In order for a regulatory inspector to verify the net content in volume, he would need to be able to accurately obtain the net contents. This would likely mean that the packaging would have to be punctured or otherwise destroyed, in order to obtain the correct volume. How would you recommend volume be accurately determined? Would volume if dispensed be based on what is "delivered"?

- We recommend that a regulatory inspector use the same method that the maker of PURE CITRUS uses to accurately determine net content of the active ingredients; i.e. the PURE CITRUS fragrance extract. They would use a simple tool that the maker can provide or even more simply empty the can in a few seconds by using the nozzle spray to spray the droplets of fragrance extract from contents of the can into a container where the droplets will condense to form a liquid volume. The container can be a laboratory graduate marked with volume markers that permit measurement of volume in fluid ounces to compare against the net fluid ounces indicated on the can. This does not require puncturing or otherwise destroying the can in order to obtain the correct volume.
- Even a consumer could use a similar measurement method to the one described above to verify the accuracy of the PURE CITRUS contents in volume. Using the same technique, consumer would simply empty the can in a few seconds by using the nozzle spray to spray the droplets of fragrance extract from contents of the can into a standard glass measuring pitcher where the droplets will condense to form a liquid volume. The glass measuring pitcher would have fluid measuring marks on the side. The consumer would then read the amount of fluid ounces corresponding with the level of the liquid in the pitcher.
- The method recommended above would measure accurately the volume dispensed of what is "delivered"; namely, the pure fragrance extract in the can. This is in contrast to the "deliverables" dispensed in a conventional aerosol spray like Glade that include small amounts of fragrance extract, and much larger amounts of noxious gas propellant, odor reducers, and water.
- The volumetric measurement method recommended is much simpler and more useful than the standard methods inspectors use to measure the net weight of "net weight" in a conventional aerosol spray like Glade. Currently, placing a can of conventional aerosol spray on a weight scale will give net weight of the entire contents of the can, but will not give the net weight of the useful part of the net weight that contain the active deliverables the consumer is paying for.
- To achieve the same results as the recommended volumetric measurement, an inspector would have to buy multiple cans of conventional aerosol, release the contents of one or more full cans by pressing the nozzle, and weigh the full and empty cans to obtain a comparison of a NET weight. It appears that the effort to measure the volumetric contents of the PURE CITRUS can with BOV technology would be easier, faster and cheaper to determine compliance with the quantity of product showing on the can.

2. Is there any concern that if packaging was "destroyed" that there would be a risk of explosion or harm?

- With the recommended volumetric measurement, the can is not punctured or destroyed. Even if the PURE CITRUS can were accidentally punctured or destroyed, there is no risk of inflammability or explosion since the can contains no propellant that presents a risk of flame or explosion. The PURE CITRUS can using BOV technology uses pure air to apply pressure around the bag of contents to create the force to dispense the active ingredients. Also, if the PURE CITRUS can is accidentally punctured, the escaping air does not harm the environment.
- In contrast, conventional aerosols generally use a flammable propellant, such as isobutene and propane and their labeling warns consumers to keep the can away from flames. But a conventional aerosol dispersion makes an impressive blow torch when sprayed across a flame.

3. It appears your product is marketed in the same category and very similar to aerosol deodorizers. How do consumers compare value if one product is sold by weight and the other by volume?

- Consumers cannot compare the net quantity of active ingredients of any of the aerosols currently on the market.
- Until and unless NIST guidelines require a declaration of the weight or volume of active ingredients, the consumer can make no comparison of price or quantity as to the actual commodity that the consumer wants, that is, the active ingredients.
- Net weight of the entire contents of the can is not what consumers are buying.
- Consumers are deceived into believing that net weight is the active ingredients.
- Active ingredients vary from one product to another.
- The current firmly established trade custom of declaring net weight is misleading and deceptive.
- The current firmly established trade custom of declaring net weight does not permit the consumer to make comparisons of price or quantity of active ingredients.

4. Below is a definition I found online.

aer•o•sol
—noun

1. Physical Chemistry . a system of colloidal particles dispersed in a gas; smoke or fog.
2. a liquid substance, as a disinfectant or deodorant, sealed in a metal container under pressure with an inert gas or other activating agent and released as a spray or foam through a push-button valve or nozzle: an aerosol for cleaning ovens.

Based on this definition, Pure Citrus would seem to fit this category. Any thoughts?

- ✓ **it is a liquid substance**
- ✓ **it is sealed in a metal (aluminum) container**
- ✓ **it is under pressure**
- ✓ **has an activating agent (air)**
- ✓ **is released as a spray through a push button**

My thoughts are as follows:

First, based on this definition, PURE CITRUS does not fit this category .

- The liquid substance is not sealed in a metal container.
- It is sealed in a bag inside of a metal container.
- The word “sealed” is derived from the noun “seal” defined as “a tight and perfect closure: or the verb “seal” defined as “to make secure against access, leakage, by a fastening or coating.” Webster’s Ninth New Collegiate Dictionary, 1991.
- The liquid is “sealed” by the enclosure bag, not by the can under these definitions.
- The bag containing the liquid substance is separate and apart from the metal container.
- The sealing of the liquid substance in a separate bag is crucial to BOV technology.
- The activating ingredient (air) is not released as a spray through a push button.
- The activating ingredient (air) remains in the can.

Second, you picked a definition of “aerosol” from the science of Physical Chemistry. I submit that the proper definition to be used is the one best understood by consumers who typically buy and use aerosol sprays. In our earlier letter, we simply used the definition readily at hand in a Webster’s New World Collegiate Dictionary, a definition a typical consumer would understand. Further, in the earlier letter, we tried to use the term “conventional aerosol” for the main part of our discussions to emphasize whatever definition is used, PURE CITRUS with the BOV technology is fundamentally different than an aerosol.

For these two reasons, I suggest that the PURE CITRUS product is not an “aerosol” or “a similar pressurized container” within the meaning of the NIST guidelines.

The National Conference on Weights and Measures recommends all aerosol packages and similar pressurized containers be labeled by net weight. (The PURE CITRUS product is not an “aerosol” or “a similar pressurized container” for the reasons stated above) **The reasons for recommending such changes are as follows:**

1. Net quantity labeling of aerosol packaged products in terms of net weight is a firmly established trade practice for such products.

- I agree.

- The current method of selling does not disclose the weight of active ingredients.
- Failure to disclose or declare the weight of volume of active ingredients misleads and deceives consumers.

2. Net quantity labeling of aerosol packaged products (and similar pressurized containers) in terms of volume is difficult (if not impossible) to verify with consumer verification methods or by conventional package inspection methods. State or local enforcement action is discouraged by such labeling.

- This is true of aerosol packaged products.
- It is not true for the substantially different PURE CITRUS non-aerosol product.
- The measurement method described above for the quantity of active ingredients in PURE CITRUS is not difficult to verify with consumer verification methods or by package inspection methods.

3. Since the labeling of aerosol packaged products (and similar pressurized containers) by volume cannot be compared with the labeling of such products in terms of net weight, labeling in terms of volume and weight inhibits value comparisons and causes consumer confusion with respect to the quantity of products the consumer is buying and can be a form of deceptive labeling.


- As indicated above, the consumer can easily empty the contents of PURE CITRUS to verify the labeled fluid content.
- A more accurate and less misleading format is to require aerosol spray products to display the amount of **active ingredients** to be delivered—either by weight or by volume.
- The consumer is not buying the aerosol can for the amount of isopropane and butane in the can.
- The consumer is primarily interested in the end result—here, a pleasant dispersed fragrance in a room or other area.
- An aerosol can that is labeled with the active ingredients, weight or volume would help establish the true value to the consumer.
- The propellants, water, and other miscellaneous ingredients would not be included in the net weight (or volume) designations, and be a more accurate amount of the delivered active ingredient to the consumer.
- The PURE CITRUS product already shows on the label the amount of active ingredients, because of its BOV technology allows the active ingredients in the bag to be separated from the compressed air around the bag.

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4. Uniformity between all state and federal regulations is highly desirable for both enforcement and fair competition in the marketplace. The Uniform Packaging and Labeling Regulation and the FTC and EPA Regulations require net quantity labeling of aerosol packaged products in terms of net weight.

- Uniformity is desirable for aerosol packaged products.
- FDA regulations already permit net quantity labeling of food products by volume.
- PURE CITRUS is not an aerosol packaged product.
- Therefore, PURE CITRUS is not subject to these aerosol based uniform standards.
- Pressurized products with BOV Technology are not aerosols or a "similar pressurized package" for which the current NIST guidelines were apparently drafted and have been applied.
- Alternatively, the makers of PURE CITRUS requests a waiver of compliance with the current guidelines.
- Either solution will avoid misunderstandings by state authorities, like Mr. Carroll in Massachusetts.

Yours truly,



Paul G. Van Slyke
PCV/ljb