Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE

1. **Date:** March 15, 2000

2. **Notifying Party:**

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4. **Description of the Proposed Action**

This notification is submitted with respect to an amorphous hydrogenated carbon (a-C:H) coating that will be applied to the interior (food-contact) surface of polyethylene terephthalate (PET) containers intended to package food.

By way of background, Sidel S.A. is a French conglomerate that specializes in the manufacture of capital equipment for the packaging industry. In 1999, the company developed and patented a system for the high speed application of a plasma-produced carbon coating on the interior wall of PET containers. This coating provides a superior gas permeation barrier that offers characteristics similar to glass. The system is known commercially by the acronym ACTIS (amorphous carbon treatment on interior surface).

The food-contact substance consists of a very thin coating of amorphous hydrogenated carbon on the interior of the container. The coating is produced in a microwave plasma using acetylene as the carbon source. The coating provides an excellent barrier to gasses such as oxygen and carbon dioxide resulting in extended shelf life for oxygen-sensitive foods and beverages.

The amorphous hydrogenated carbon coating is intended for use at a level not to exceed approximately 0.15 microns thick (0.006 mil) and may be used in contact with aqueous, acidic, alcoholic, fatty, and dry foods, at temperatures up to or above 100°C (212°F). Thus, the carbon coating will be used in contact with food types I through IX, under Conditions of Use A through H, as described in Tables 1 and 2 of 21 C.F.R. § 176.170(c).

PET containers produced with the amorphous hydrogenated carbon coating are expected to be used primarily to hold beverages. These may include nonalcoholic soft drinks, juice drinks, and low-alcohol beverages such as beer, although other foods and beverages could be packaged in the containers as well, such as water, food oils, etc. The containers are expected to vary in size according to the demands of the end-use application.

5. Environmental consequences of the proposed action:

a. Production of the food-contact substance

The Food and Drug Administration has advised that environmental assessments no longer must routinely provide information on the introduction of substances to the environment resulting from the manufacture of food-contact substances. No extraordinary circumstances apply to the manufacture of amorphous hydrogenated carbon coatings by the Notifier's ACTIS system. Indeed, as discussed elsewhere in this Notification, the coating is applied to the inner surface of blown bottles in a process that involves the complete consumption of the acetylene starting material so that no wastes or emissions are generated in the process. Consequently, environmental introductions and controls exercised at the site of production of the subject coating are not addressed here.

b. Use and disposal of the food-contact substance

PET containers made with the subject coating are expected to be disposed of in patterns similar to the current disposal of conventional PET containers. This statement is supported by data discussed below, which demonstrate that the bottles may be included in PET recycling streams without adverse affects to the recycled product.

Thus, in keeping with established disposal patterns for PET bottles, it is expected that about 40% of beverage containers and 12.8% of custom bottles will be recycled.[14/] The remaining containers are expected to be disposed of in accordance with usual solid waste

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[14/] The U.S. Environmental Protection Agency. *Characterization of Municipal Solid Waste in the United States: 1997 Update.* Report No. EPA 530-R-98-007, May 1998, Washington, DC.

disposal patterns; thus, about 76% of the containers not recycled will be disposed of by means of landfill and 24% will be incinerated.

Disposal of the coated containers by means of sanitary landfills will not result in any significant amount of leaching into the environment due to the extreme stability of the coating and its location on the interior surface of the bottles, and the Environmental Protection Agency's regulations in 40 C.F.R. part 258 that place requirements on solid-waste landfills intended to limit leaching to the surrounding environment. Moreover, when properly incinerated, the coatings, which are composed of carbon, hydrogen, and oxygen, will generate no hazardous emissions.

For these reasons, the only potential impact resulting from the use and disposal of ACTIS coated PET containers would be effects on established PET recycling systems due to the inclusion of coated PET bottles in general PET bottle recycle streams. Because the bottles are expected to be collected with other, non-coated PET bottles and to be recycled with such containers, the Notifier arranged to have a series of studies conducted by two companies that are leaders in PET recycling to determine whether the presence of the coated bottles among conventional bottles collected for recycling will adversely affect the processing of the PET recycle or the properties of materials produced from recycled PET flake.

In this regard, as indicated above, the coating is applied in an extremely thin layer no more than 0.15 micron in thickness. The existence of such a thin amorphous hydrocarbon layer on the surface of the bottle is unlikely to have any impact on the physical properties of recycled PET. However, due to a slight yellowish tint, it is conceivable that mixing of coated and non-coated bottles could have an impact on the color of the recycled product. For this reason, the recycling studies focused largely on the color of recycle blends containing varying levels of the coated bottles; these studies also confirmed the absence of any adverse impact on physical/technical properties.

Wellman, Inc. Study

The first series of studies with clear ACTIS bottles were conducted by Wellman, Inc., the world's largest recycler of PET. A report of this testing appears in Appendix XII. As shown there, the testing was conducted in two phases. In the first phase, a series of studies were conducted using unwashed PET bottles containing the amorphous hydrogenated carbon coating; the second phase made use of washed coated PET bottles. Both phases included trials in which recycle blends were used to produce carpet and textile fibers. The study is discussed more fully below.

The first phase initially investigated, on the laboratory scale, the ability to remove the ACTIS coating using various washing procedures. Removal of the coating was gauged visually and by measuring the color of washed flake and samples extruded from the washed flake. Color parameters used throughout the study are those commonly used to assess the color of recycled PET.[15/] Promising results were achieved using both a proprietary washing process (identified as the "Wellman wash") and an industry washing protocol established by

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[15/] Specifically, the Hunter Lab parameters include a measure of the lightness/darkness of the resin, "L" (ranging from 0-black to 100-white); red/green tint, "a" (where a (+) value indicates increase in red, and (-) value indicates increase in green); and yellow/blue tint, "b" (where a (+) value means increase in yellow, and (-) means increase in blue). Removal of the coating is reflected primarily as an increase in lightness and decrease in yellowness.

the National Association for PET Container Resources (NAPCOR), as well as a commercially available wash chemistry from Mangill/PPG. These results suggest that much of the coating may be removed if the wash conditions include adequate agitation of the flake.

The next step in the Wellman testing was to examine the color of drawn fiber produced in its pilot plant from PET blends containing increasing levels of unwashed, coated bottles (identified in the report as Phase I.B, Pilot Plant Fiber Trials). In an initial, "scouting" trial on carpet fiber, based primarily on the Hunter Lab "b" color values, acceptable levels of *unwashed* bottles were up to about 12% of the recycle stream (based as a percentage of the total clear PET in post-consumer baled bottles), while concentrations of 25% or more were unacceptable.[16] This was followed by a full-scale carpet fiber trial, which confirmed that PET blends containing up to about 12% of unwashed coated bottles were acceptable, while higher levels gave an unacceptable yellow tint. This testing also indicated no adverse effects on carpet fiber dyeability for coated bottle blending levels up to 18%, the maximum level tested.

Finally, trials on drawn textile fiber, again conducted on recycle blends containing increasing levels of unwashed coated bottles, demonstrated a maximum acceptable blending level of 18% of coated bottles (again based on percentage of total clear PET in post-consumer

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[16] It should be emphasized that the "unacceptability" here was due to color only, and that there were no processing issues at levels up to 100% of coated bottles. The yellowness was measured as an increase in the "b" value, or positive "Δb." While, according to Wellman, a Δb value of greater than about 0.5 may be observed by the naked, trained eye, Δb values that fall outside the actual 3 sigma limits are unacceptable to Wellman.

baled bottles) based on a yellow tint at higher concentrations.[17] Textile fiber samples also were tested to determine the effects on physical properties of including unwashed ACTIS-coated bottles. This testing established that blends containing up to 32% coated bottles, the highest level tested, had no adverse effects on tenacity (tensile strength), elongation, or processing. These results also indicate that there is no effect on physical properties of carpet fiber as well.

The general conclusions drawn from the first phase of the recycling study are as follows: Inclusion of ACTIS-coated PET bottles in the general PET recycling stream does not adversely affect the processing of the recycle or the physical properties and dyeability of the drawn fiber. In addition, even if the bottles are not subject to any washing step, acceptable textile and carpet fiber may be produced from blends containing as much as 12% of the coated bottles. This limitation on the content of coated bottles in the recycle is based solely on a visible and measurable yellow tint at higher ACTIS concentrations.

In Phase II of the Wellman study, separate samples of the ACTIS bottles were granulated and washed according to either the Wellman or NAPCOR washing protocols. In both cases, according to the established color parameters (L, a, and b), the washing achieved essentially complete removal of the ACTIS coating; in other words, there was no visible or measurable coloration due to coating remaining on the bottle. This testing, conducted at the

[17] The color of textile fiber is evaluated using somewhat different calculation procedures than used with carpet fiber. As a result, the color values for textile fiber are presented as Cielab color values L*, a*, and b*. These color parameters have comparable definitions to the L, a, b values defined above.

pilot plant scale, achieved significantly better results than were obtained in lab washing in Phase I.

Wellman then conducted a second pilot-plant trial on carpet fiber, this time preparing resin blends with increasing content of *washed* ACTIS bottle flake. The testing conducted in Phase II focused exclusively on the fiber color; the results of Phase I removed any concern as to potential effects on dyeability, physical properties, and processing, which were not impacted even when unwashed bottles were tested.

The carpet fiber trial involved testing blends containing 10%, 25%, and 50% of washed ACTIS bottles; samples from both the Wellman wash and NAPCOR wash processes were tested. For both wash chemistries, all color parameters were found to be acceptable at ACTIS concentrations up to the maximum tested. These results are consistent with the wash trials that indicated visual and measurable removal of the coating by both standard processes.

Similar results were obtained in a pilot-plant textile fiber trial, in which fiber was drawn from blends containing 15%, 30%, or 50% of washed ACTIS bottles. Again, all color parameters were within acceptable ranges for all concentrations of coated bottles, for both samples washed using the Wellman and NAPCOR wash chemistries.

Thus, based on the results of the Phase II testing, it is apparent that ACTIS bottles may be included at levels of at least 50% of total clear PET in post-consumer baled bottles that are subject to available wash procedures. The inclusion of these bottles at such levels will have no adverse impact on color, physical properties, dyeability, or processing. Indeed, based on the pilot plant wash trials which demonstrated complete removal of coating by visual and measurable determinations, it appears that ACTIS bottles could represent as much as 100% of clear PET bottle recycle without adverse impact on the fiber color. Considering the testing conducted on unwashed bottles, it is clear that there also will be no impact on other properties affecting the utility of the fiber, including dyeability, physical properties, and processing.

PTI Study

In addition to the fiber testing discussed above, the impact of ACTIS-coated bottles on bottle-to-bottle recycling has also been thoroughly investigated. This testing was conducted by a leader in PET bottle-to-bottle recycling processes, Plastic Technologies, Inc. (PTI); a report of the study appears in Appendix XIII. The testing involved grinding blown ACTIS-coated and control (uncoated) bottles to produce flakes and washing separate samples of the coated bottle flakes according to the Wellman and NAPCOR wash protocols. The sample and control flakes were then pelletized, and subjected to solid stating to increase the intrinsic viscosity (IV) to the required value of >0.82 and <0.86. The test and control pellets were then blended with virgin PET resin at levels of 20%, 40%, 60%, and 100%. The various pellet blends were injection molded to produce bottle preforms, which were then blow-molded to produce finished 2-liter bottles.

The effect of the ACTIS coating on recycling was analyzed by testing relevant properties of the various samples at each stage of processing. Thus, the washed flake and pellets produced from the ACTIS bottles were tested to determine the IV and the color; the latter was assessed using the same parameters (L*, a*, b*) employed in the fiber studies. Samples prepared from washed ACTIS bottle flake underwent a decrease in IV upon pelletizing similar to that of controls. At both the washed flake and pellet stage, there was a visible color difference, with the ACTIS-coated bottles having a more yellow tint (greater "b" value) than the uncoated control bottles.

At the solid-stated pellet stage, the IV and color again were determined. In this case, the concentration of acetaldehyde (AA) in the solid-stated pellet also was determined. Here, the pellets produced from washed ACTIS flake still retained a slightly more yellow tint than the controls, but there was no difference in the AA content.

Injection-molded preforms produced from pellet blends of washed ACTIS bottle flake and virgin PET were again tested for IV, color, and the AA content, as well as for haze. At the preform stage, there still remained a higher "b" value (greater yellow tint) in blends containing the amorphous carbon coating as compared with controls consisting of 100% virgin PET. The ACTIS blend samples also were found to be less hazy than the virgin PET controls and to contain slightly more AA.

Finally, the blown bottles produced from the sample and control preforms were compared. The bottles were tested for color and haze and for AA in the bottle's headspace (AAH); this is a concentration of AA measured in micrograms related to the volume of the bottle in liters. In addition, a series of tests were conducted to determine the physical properties including top load, burst stress, and drop resistance, creep testing, and effect on carbon dioxide permeability. All physical properties were acceptable for the full range of ACTIS flake blend concentrations up to 100%. Haze and AAH values were comparable across the range of samples tested as well. In addition, for the finished blown bottle, all color values were within acceptable limits for samples containing up to 40% of washed ACTIS flake. The samples containing higher ACTIS levels were slightly yellower than the controls.

Thus, although a visible difference in yellowness persisted for the ACTIS samples from the washed flake through the injection-molded preform stages, the finished containers were acceptable in all parameters for blends produced from as much as 40% of ACTIS coated bottles.

Conclusions

Taken in their entirety, the studies conducted by Wellman and PTI demonstrate that the presence of ACTIS coated bottles in the general PET recycling stream will have no adverse impact on the utility of the recycled PET for use in a wide range of applications for post-consumer PET. The fact that the bottle-to-bottle recycling study suggested a maximum allowable content of 40% of the washed ACTIS bottle flake due to a slight yellow tint at higher levels does not suggest a problem for recycling because this maximum blending ratio in most cases significantly exceeds the recycle content typical of bottles produced with post-consumer PET, and because it is unlikely that 100% of any recycle batch would consist of ACTIS-coated bottles. The carpet and textile fiber testing did not suggest any problems relating to color or other properties at the highest blending levels tested. Consequently, it may be concluded that the subject amorphous hydrogenated carbon coating may be used as intended with no adverse effect on recycling programs for PET.

As discussed above, no other potential adverse environmental impacts associated with the use and disposal of PET containers produced with the ACTIS coating have been identified. Thus, considering the foregoing, it may be concluded that the use of the coating on the interior surface of PET containers will have no significant adverse environmental impact.

6. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects are anticipated.

7. List of Preparers

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Qualifications: Over 15 years experience in preparing environmental assessments for food-contact substances.

8. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best knowledge of Sidel S.A.

Date: March 15, 2000

George G. Misko
Counsel for Sidel S.A.