

M&T Chemicals Inc.

SUBSIDIARY OF AMERICAN CAN COMPANY



GENERAL OFFICES, RAHWAY, NEW JERSEY 07063

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AN 1483
dated

October 21, 1969

Dr. Alexander P. Mathers
Chief Laboratory Branch
Alcohol, Tobacco & Firearms Division
Internal Revenue
1111 Constitution Avenue, N.W.
Washington, D. C. 20250

Dear Dr. Mathers:

As requested by members of the Alcoholic Beverage Industry, PVC bottle manufacturers and PVC compound manufacturers, we have completed the testing of alcoholic beverages in Octyltin stabilized PVC bottles. The evaluation program was outlined in our report to you dated 9/19/69. The results of this testing, as attached, confirm that Octyltin stabilized PVC is suitable for packaging of distilled spirits and further that simulated testing following the time/temperature conditions as outlined in FDA Regulation 21CFR 121.2526(c) is practical. Accordingly, we request that the Alcoholic Beverage Industry be advised that:

PVC stabilized with di-n-octyl tin compounds outlined in FDA Regulation 21CFR 121.2602, intended for packaging of distilled spirits shall be tested for tin transfer under the conditions outlined in FDA Regulation 121.2526(c) using distilled spirits or as the simulating solvents, 8% ethyl alcohol or 50% ethyl alcohol, whichever is appropriate. Time/temperature storage conditions shall be as outlined in FDA Regulation 121.2526(c).

Very truly yours,

M&T CHEMICALS INC.

A. W. Sheldon
Manager of Product Registration

W. A. Larkin
Market Manager

AWS:WAL:bad

cc: Mr. J. G. Kaplan - M&T Chemicals
Mr. R. J. Zedler - M&T Chemicals
Mr. J. Asbeck - B. F. Goodrich
Mr. M. Smith - Owens-Illinois
attach.

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TIN TRANSFER DATA FOR ALCOHOLIC BEVERAGE PACKAGING

The PVC bottles used for the first series in this study were prepared by Owens-Illinois using Geon 85658 PVC compound manufactured by the B. F. Goodrich Chemical Company and M&T Food Grade Octyltin stabilizers. They were filled with Bourbon Supreme, an 86 proof straight whiskey, which is a product of the American Distilling Company, Inc. These containers were one-half gallon in size and provided 122 square inches of exposed surface area. This is equivalent to 15.5 ml of distilled spirits per square inch of surface area.

The second series of PVC bottles used was also prepared from Geon 85658. This series consisted of 16 ounce cylinders manufactured in the B. F. Goodrich Laboratories. They were filled with 86 proof bourbon whiskey manufactured by the Seagram Company. These containers provided 58 square inches of exposed surface area, equivalent to 8.6 ml of distilled spirits per square inch of surface area.

All test containers were placed in an air-circulating oven and controlled at the desired test temperature. The caps of the containers were loosened periodically while the contents were being heated to the test temperature. At that point the caps were tightly sealed.

1. Tests with PVC Bottles - "Ramsey Procedure"

In this study the test containers were heated to $135 \pm 5^{\circ}\text{F}$ to establish the maximum amount of organotin stabilizer transferred. These tests were conducted at one and three weeks, at which time the plateau value was reached. The following data has been obtained:

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	<u>Series I</u>		<u>Series II</u>	
	<u>ppm (mg/liter)</u>		<u>ppm (mg/liter)</u>	
	<u>Tin</u>	<u>Stabilizer</u>	<u>Tin</u>	<u>Stabilizer</u>
1 week	0.03	0.19	0.02	0.13
3 weeks	0.02	0.13	-	-
Control	none found	-	none found	-

- 2. Tests with PVC Bottles - Procedure of 121.2526(c)

Tests were conducted in accordance with 121.2526(c) Table 2.

The conditions of use selected were:

D. hot filled or pasteurized below 150°F

E. room temperature filled and store (no thermal treatment in the container).

On this basis, tests were performed at 150°F for 2 hours and 120°F for 24 hours.

Although alcoholic beverages are packaged, stored and shipped at room temperature, we have included higher temperature testing (150°F) to demonstrate that octyl tin stabilized PVC is satisfactory from the point of view of tin transfer even at these impractical temperatures.

To further demonstrate that these conditions were practical for rapid testing, the above tests were carried to equilibrium.

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	<u>Series I</u>		<u>Series II</u>	
	<u>ppm (mg/liter)</u>		<u>ppm (mg/liter)</u>	
	<u>Tin</u>	<u>Stabilizer</u>	<u>Tin</u>	<u>Stabilizer</u>
<u>150°F</u>				
2 hours	0.03	0.19	0.02	0.13
4 hours	0.03	0.19	0.03	0.19
6 hours	-	-	0.03	0.19
Control	none found	-	0.01	0.06
<u>120°F</u>				
24 hours	0.03	0.19	0.02	0.13
48 hours	0.03	0.19	0.02	0.13
Control	none found	-	0.01	0.06

3. Tests with PVC Bottles - Exaggerated Conditions

In an effort to determine the effect of exaggerated conditions of test, we exposed sample bottles as above to 150°F for 3 days. Although the amount of tin transfer was higher, it was still significantly below the maximum allowable limit of 1 ppm. It should be noted that these conditions of test resulted in a very distorted container as well as a loss of clarity of the PVC, indicating that such exposure would result in unsalable containers. These conditions are illustrated in the photographs we have prepared.

	<u>Series I</u>		<u>Series II</u>	
	<u>ppm (mg/liter)</u>		<u>ppm (mg/liter)</u>	
	<u>Tin</u>	<u>Stabilizer</u>	<u>Tin</u>	<u>Stabilizer</u>
3 days at 150°F	0.06	0.38	0.10	0.63
Control	none found	-	0.01	0.01

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4. Tests with Pressed Sheets - Simulated Media

These test samples were made with 2 grams of Thermolite® 831 to 100 grams of PVC Resin. The test sheets were cut to 3" x 5" sizes and were 20 mils thick. Ten test sheets were used for each extraction for a total of 300 square inches in contact with 750 ml of 50% ethyl alcohol (100 proof). This test was run at 135°F.

	ppm (mg/liter)	
	<u>Tin</u>	<u>Stabilizer</u>
1 week	0.12	0.76
2 weeks	0.12	0.76
3 weeks	0.12	0.76

SUMMARY

The PVC Stabilizers, di(n-octyl) tin S,S' bis (isooctyl mercapto acetate) and di (n-octyl) tin maleate polymer, meeting the specifications set forth in FDA Regulation 121.2602 are sanctioned for use by the FDA in PVC intended for use in packaging of distilled spirits (with the exception of malt liquors).

This regulation further states that no more than 3 parts per hundred of these stabilizers (total) may be used in the PVC and the packaged materials shall not contain more than 1 part per million of the stabilizer.

The data presented shows that the stabilizers do not transfer to distilled spirits in excess of 1 ppm. Further, transfer testing using the time/temperature conditions of 121.2526(c) correlates with long term testing to equilibrium at $135 \pm 5^\circ\text{F}$ and that such accelerated testing is practical as a means of evaluating PVC compounds intended for use in distilled spirits packaging and for quality control purposes.

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