

2/15/23

**ARC S3 – FDA / FOOD GRADE COMPLIANCE STATEMENT**

A.W. Chesterton Company  
 860 Salem St.  
 Groveland, MA 01834

This is to confirm that Chesterton product **ARC S3** complies with 21CFR 175.300 and is intended to come into direct food contact; manufactured in accordance to Chesterton’s control procedure “**IL/ARC Current Good Manufacturing Practices (cGMP)**”.

The tests were carried out as per 21CFR 175.300(d) Table 2, conditions B, C and 21CFR 175.300(e). The ARC S3 product meets the extraction requirements for use as a coating in contact with Type II, III, and VII foods under Condition B (boiling water sterilized) for single and repeated use container applications. The ARC S3 product meets the extraction requirements for use as a coating in contact with Type II, III, IV-A, IV-B & V foods under Condition C (hot filled or pasteurized above 150° F) for single and repeated use container applications. The coating also complies with 21CFR 175.300 for Type II, III, IV-A, IV-B, V food types & Type VII foods stored under Condition C in contact with the coating.

**CONDITION B**

<b>Food simulating solvent:</b>	<b>Distilled Water</b>
Exposure Conditions: 21CFR 175.300 (e) (4)(ii)	Boiling solvent to test coupons and allow extraction; 30 minutes at 212° F
<b>Results</b>	<b>mg extraction residue / in2 of coating exposure</b>
21CFR 175.300 (e ) Extraction	Trial 1    Trial 2    Trial 3    Average (mg/in2)
Condition B: Distilled Water: 30 minutes at 212° F	0.12    0.11    0.13 <b>0.12</b>
<b>Food simulating solvent:</b>	<b>Heptane</b>
Exposure Conditions: 21CFR 175.300 (e) (4)(x)	120° F Heptane for 30 minutes
<b>Results</b>	<b>mg extraction residue / in2 of coating exposure</b>
21CFR 175.300 (e ) Extraction	Trial 1    Trial 2    Trial 3    Average (mg/in2)
Condition B: Heptane for 30 minutes at 120° F (includes factor of 5 reduction per 21CFR175.300(e)(i)(b))	0.043    0.044    0.041 <b>0.043</b>

**Requirements per 21CFR 175.300(c) (maximum allowed for any extraction condition):**

Single-use containers <= 1 gallon: 0.5 mg/in2  
 Single-use containers > 1 gallon: 1.8 mg/in2  
 Repeated-use: 18mg/in2

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**CONDITION C**

<b>Food simulating solvent:</b>	<b>Distilled Water</b>
Exposure Conditions: 21CFR 175.300 (e) (4)(iii)	Add boiling solvent to test coupons and allow extraction test to continue until temperature falls to 100° F,
<b>Results</b>	<b>mg extraction residue / in<sup>2</sup> of coating exposure</b>
21CFR 175.300 (e) Extraction	Trial 1 Trial 2 Trial 3 Average (mg/in <sup>2</sup> )
Condition C: Distilled Water: Fill boiling, cool to 100° F	0.11 0.094 0.098 <b>0.10</b>
<b>Food simulating solvent:</b>	<b>Heptane</b>
Exposure Conditions: 21CFR 175.300 (e) (4)(iii)	120° F heptane for 15 minutes
<b>Results</b>	<b>mg extraction residue / in<sup>2</sup> of coating exposure</b>
Condition C: Heptane: 15 minutes @ 120° F	<i>See results for Heptane 30 minutes at 120° F</i>

**Requirements per 21CFR 175.300(c) (maximum allowed for any extraction condition):**

 Single-use containers <= 1 gallon: 0.5 mg/in<sup>2</sup>

 Single-use containers > 1 gallon: 1.8 mg/in<sup>2</sup>

 Repeated-use: 18mg/in<sup>2</sup>

21 CFR 175 Indirect food Additives: Adhesive and Components of Coatings							
21 CFR 175.300 Resinous and Polymeric Coatings – Table 2							
Conditions of Use: D, E and F							
Sample: Epoxy resin coating							
Analyte	Distilled			n-Heptane	8% Ethanol / Distilled		Pass / Fail
	Water				Water		
Test Conditions	150° F-2 hours	120° F-24 hours	70° F- 48 hours	100° F-2 hours	150° F-2 hours	120° F-24 hours	
Results	<0.1 mg/in <sup>2</sup>	<0.1 mg/in <sup>2</sup>	<0.1 mg/in <sup>2</sup>	<0.1 mg/in <sup>2</sup>	<0.1 mg/in <sup>2</sup>	<0.1 mg/in <sup>2</sup>	<b>PASS</b>

Materials shall be Generally Considered As Safe (GRAS) as demonstrated under FDA's implementing regulations in 21CFR 170.3 and 21CFR 170.30. Traceability is assured via compliance with the requirements of AWC Groveland Business Management System Manual Revision K, dated January 14, 2020 and control procedure "IL/ARC Current Good Manufacturing Practices (cGMP)".



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