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To: General Distribution
 From: Technical Service
 Date: 3/7/2023
 Subject: Norseal Silicone FDA 21 CFR 177 2600 Extractables

CFR Title 21 Section 177.2600 covers the use of rubber articles with aqueous foods and fatty foods. NORSEAL® silicone foams: **F12 Grey, F12 Black, F15 Grey, F20 Grey, F20 Black, R10400 Grey, R10404 Green, R10460 Blue, R10470M Orange/Tan, R10470F Orange/Tan, R10480 Medium Brown, R10480 Soft Red and 9050 Red, SNS 100S Orange/Tan, SNS 200A Orange/Tan, SNS 512AF Grey, SNS 520AF Grey** have been tested using CFR Title 21 Section 177.2600. The test reports, done by Akron Rubber Development Laboratory (ARDL), are available on request through your local Saint-Gobain Foams representative.

NORSEAL F12 Silicone Foam

Table 1. NORSEAL Silicone Foam F12 Black CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
F12 Black	First 7 hrs.	Distilled Water	1.9	20	PASS
	Next 2 hrs	Distilled Water	0.09	1	PASS
	First 7 hrs.	N-Hexane	4.5	175	PASS
	Next 2 hrs	N-Hexane	0.06	4	PASS

Note: Data from ARDL PN 128414

Table 1A NORSEAL Silicone Foam F12 Gray CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
F12 Grey	First 7 hrs.	Distilled Water	0.6	20	PASS
	Next 2 hrs	Distilled Water	1.0	1	PASS
	First 7 hrs.	N-Hexane	12.6	175	PASS
	Next 2 hrs	N-Hexane	1.2	4	PASS

Note: Data from ARDL PN 128414

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Table 2. NORSEAL Silicone Foam F15 GR CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
F15 Grey	First 7 hrs.	Distilled Water	0.2	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	5.5	175	PASS
	Next 2 hrs	N-Hexane	0.2	4	PASS

Note: Data from ARDL PN 170068

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NORSEAL F20 Silicone Foam

Table 3. NORSEAL Silicone Foam F20 Grey CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
F20 Grey	First 7 hrs.	Distilled Water	1.1	20	PASS
	Next 2 hrs	Distilled Water	0.1	1	PASS
	First 7 hrs.	N-Hexane	8.1	175	PASS
	Next 2 hrs	N-Hexane	0.5	4	PASS

Note: Data from ARDL PN 128414

Table 4. NORSEAL Silicone Foam F20 Black CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
F20 Black	First 7 hrs.	Distilled Water	0.5	20	PASS
	Next 2 hrs	Distilled Water	0.08	1	PASS
	First 7 hrs.	N-Hexane	14.7	175	PASS
	Next 2 hrs	N-Hexane	0.8	4	PASS

Note: Data from ARDL PN 128414

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NORSEAL R10400 Silicone Sponge

Table 5. NORSEAL Silicone Foam R10400 Grey CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10400 Grey	First 7 hrs.	Distilled Water	1.0	20	PASS
	Next 2 hrs	Distilled Water	0.05	1	PASS
	First 7 hrs.	N-Hexane	12.8	175	PASS
	Next 2 hrs	N-Hexane	1.8	4	PASS

Note: Data from ARDL PN 128414

NORSEAL R10404 Medium ThermalCool Silicone Sponge

Table 6. NORSEAL R10404 Medium Green CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10404 Green	First 7 hrs.	Distilled Water	0.3	20	PASS
	Next 2 hrs	Distilled Water	0.2	1	PASS
	First 7 hrs.	N-Hexane	6.8	175	PASS
	Next 2 hrs	N-Hexane	0.4	4	PASS

Note: Data from ARDL PN 157699-A

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NORSEAL R10460 Silicone Sponge

Table 7. NORSEAL R10460 Blue CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10460 Blue	First 7 hrs.	Distilled Water	0.1	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	7.9	175	PASS
	Next 2 hrs	N-Hexane	0.3	4	PASS

Note: Data from ARDL PN 157699-C

NORSEAL R10470 Medium Silicone Sponge

Table 8. NORSEAL R10470 Medium Orange / Tan CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10470 Medium Orange/ Tan	First 7 hrs.	Distilled Water	0.7	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	8.6	175	PASS
	Next 2 hrs	N-Hexane	0.4	4	PASS

Note: Data from ARDL PN 15327-B

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NORSEAL R10470 Firm Silicone Sponge

Table 9. NORSEAL R10470 Firm Orange/Tan CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10470 Firm Orange/ Tan	First 7 hrs.	Distilled Water	0.4	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	6.6	175	PASS
	Next 2 hrs	N-Hexane	0.3	4	PASS

Note: Data from ARDL PN 157699-B

NORSEAL R10480 Medium Silicone Sponge

Table 10. NORSEAL R10480 Medium Brown CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10480 Medium Brown	First 7 hrs.	Distilled Water	0.9	20	PASS
	Next 2 hrs	Distilled Water	0.2	1	PASS
	First 7 hrs.	N-Hexane	6.0	175	PASS
	Next 2 hrs	N-Hexane	0.4	4	PASS

Note: Data from ARDL PN 15327-A

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NORSEAL R10480 Soft Silicone Sponge

Table 11. NORSEAL R10480 Soft Red CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
R10480 Soft Red	First 7 hrs.	Distilled Water	0.7	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	7.3	175	PASS
	Next 2 hrs	N-Hexane	0.5	4	PASS

Note: Data from ARDL PN 153274-C

NORSEAL 9050 Silicone Solid

Table 12. NORSEAL 9050 Red CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
9050 Orange	First 7 hrs.	Distilled Water	0.5	20	PASS
	Next 2 hrs	Distilled Water	0.1	1	PASS
	First 7 hrs.	N-Hexane	27.2	175	PASS
	Next 2 hrs	N-Hexane	3.0	4	PASS

Note: Data from ARDL PN 128414

NOTE: The table is a reprint of test results done at an independent laboratory, and actual results may vary from lot to lot of product. The actual test results should be reviewed as part of a product submission and in the event of a discrepancy the test report values are the original data.

Because Saint-Gobain cannot anticipate or control every potential application, we strongly recommend testing the product under individual application conditions prior to use. Please contact your local Saint-Gobain Tape Solutions representative for additional support if needed.

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NORSEAL SNS 100S Orange / Tan

Table 13. SNS 100S Orange / Tan CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
SNS 100S Orange / Tan	First 7 hrs.	Distilled Water	0.2	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	27.2	175	PASS
	Next 2 hrs	N-Hexane	2.7	4	PASS

Note: Data from ARDL PN 157698-A

NORSEAL SNS 200A Orange / Tan

Table 7. NORSEAL SNS 200A Orange / Tan CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
Norseal SNS 200A	First 7 hrs.	Distilled Water	0.6	20	PASS
	Next 2 hrs	Distilled Water	0.01	1	PASS
	First 7 hrs.	N-Hexane	11.1	175	PASS
	Next 2 hrs	N-Hexane	3.2	4	PASS

Note: Data from ARDL PN 157698-B

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NORSEAL SNS 512AF Grey

Table 7. NORSEAL SNS 512AF Grey CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
Norseal SNS 512AF	First 7 hrs.	Distilled Water	0.1	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	27.4	175	PASS
	Next 2 hrs	N-Hexane	1.3	4	PASS

Note: Data from ARDL PN 157698-C

NORSEAL SNS 520AF Grey

Table 7. NORSEAL SNS 520AF Grey CFR Title 21 Section 177.2600 Extraction test results

SAMPLE	EXTRACTION TIMES	SOLVENT	Measured EXTRACTABLE CONTENT mg/in ²	CFR Title 21 Section 177.2600 REQUIREMENT mg/in ² max	PASS/FAIL
Norseal SNS 520AF Grey	First 7 hrs.	Distilled Water	0.6	20	PASS
	Next 2 hrs	Distilled Water	None Detected	1	PASS
	First 7 hrs.	N-Hexane	10.1	175	PASS
	Next 2 hrs	N-Hexane	0.9	4	PASS

Note: Data from ARDL PN 157698-D