

TAN PHU VIET NAM JOINT STOCK COMPANY

314 Luy Ban Bich, Hoa Thanh, Tan Phu, Ho Chi Minh City.

Test Report

SAMPLING:	Sample Not Drawn By Eurofins Consumer Product Testing Vietnam Co. Ltd
SAMPLE DESCRIPTION:	BÌNH SỮA AOI
COUNTRY OF ORIGIN:	N/A
EXPORT TO:	USA
DELIVERY CONDITION:	Sample Received in Good Condition
RECEIVED ON:	28/09/2023
TESTING PERIOD:	28/09/2023 – 09/10/2023

RESULT SUMMARY

#	TEST REQUESTED	PASS	FAIL	DATA
I.	US. FDA. 21.CFR Part 177.1520 - Density - Melting point - Maximum Extractable Fraction - n-Hexane - Maximum Soluble Fraction - Xylene	X		
II.	Requirements for Rubber articles intended for repeated use - United States Code of Federal Regulations (CFR), Title 21, Section 177.2600 - Total extractives of food contact surface: Distilled water - Total extractives of food contact surface: Hexane	X		
III.	Requirements for Polysulfone resins intended for repeated use - US. FDA. 21.CFR Part 177.1655 - Total extractives in Heptane - Total extractives in Distilled water	X		

Pass – Meets Performance Standard

Fail – Fails to Meet Performance Standard

***** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) *****

This test report has been validated by:

Henry Nguyen
 General Manager SL & AN

Results obtained refers to the samples, products or materials received in the Laboratory, as described in above related sample description, and tested in conditions shown in present report. Eurofins Consumer Product Testing Vietnam Co., Ltd. ensures that this job has been performed according to our Quality System and complying contract and legal conditions. Reproduction of this document is only valid if it is done completely and under the written permission of Eurofins Consumer Product Testing Vietnam Co., Ltd. If you have any comments or complaints, please response by sending an email to CPTVNcs@eurofins.com and referring to this report number.

SAMPLE PHOTO



M01 Cap



M02 Screw Cap



M03 Nipple needle



M04 Compartment lip



M05 Main bottle



M06 Nipple

TEST RESULT

Test Item(s)	Color	Material	Sample Location
M01	Yellow	PP	Cap
M02	Yellow	PP	Screw cap
M03	Yellow	PP	Nipple needle
M04	White	PP	Compartment lip
M05	Light Yellow	PPSU	Inside bottle
M06	Natural	Silicone	Nipple

I. DETERMINING THE AMOUNT OF EXTRACTIVES - US FDA 21 CFR 177.1520

Test method and limit with reference to US FDA 21 CFR 177.1520.

Requirement(s):		
Parameter(s)	Soluble Solvent(s) / Extraction	Limit
Density (g/cm ³)	-	0.88 to 0.913
Melting point (°C)	-	160 – 180
Maximum Extractable Fraction (%)	n-Hexane	6.4 at reflux temperature
Maximum Soluble Fraction (%)	Xylene	9.8 at 25°C

Test Item(s)	M01		
	Unit	Result	Detection limit
Density	g/cm ³	0.90	-
Melting point	°C	169.5	-
Maximum Extractable Fraction - n-Hexane (Reflux temperature, 2 hours)	%	1.6	1.5
Maximum Soluble Fraction – Xylene (120 deg. C till completely dissolved, cool to 25 deg. C)	%	7.6	1.5
Conclusion	-	PASS	-

Note / Key:

“<” = Less than

U. S. = United States

% = weight by weight percentage

g/cm³ = gram(s) per cubic centimeter

deg. C = degree Celsius (°C)

TEST RESULT

Test Item(s)	M02		
	Unit	Result	Detection limit
Density	g/cm ³	0.91	-
Melting point	°C	170.6	-
Maximum Extractable Fraction - n-Hexane (Reflux temperature, 2 hours)	%	2.3	1.5
Maximum Soluble Fraction – Xylene (120 deg. C till completely dissolved, cool to 25 deg. C)	%	3.0	1.5
Conclusion	-	PASS	-

Test Item(s)	M03		
	Unit	Result	Detection limit
Density	g/cm ³	0.91	-
Melting point	°C	169.7	-
Maximum Extractable Fraction - n-Hexane (Reflux temperature, 2 hours)	%	< 1.5	1.5
Maximum Soluble Fraction – Xylene (120 deg. C till completely dissolved, cool to 25 deg. C)	%	4.5	1.5
Conclusion	-	PASS	-

Note / Key:

"<" = Less than

 g/cm³ = gram(s) per cubic centimeter

U. S. = United States

 % = weight by weight percentage
 deg. C = degree Celsius (°C)

TEST RESULT

Test Item(s)	M04		
	Unit	Result	Detection limit
Density	g/cm ³	0.90	-
Melting point	°C	170.5	-
Maximum Extractable Fraction - n-Hexane (Reflux temperature, 2 hours)	%	< 1.5	1.5
Maximum Soluble Fraction – Xylene (120 deg. C till completely dissolved, cool to 25 deg. C)	%	3.5	1.5
Conclusion	-	PASS	-

Note / Key:

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g/cm³ = gram(s) per cubic centimeter

U. S. = United States

% = weight by weight percentage

deg. C = degree Celsius (°C)

TEST RESULT

II. TOTAL EXTRACTIVES IN FOOD SLIMULANTS - US FDA 21 CFR 177.2600

Test method and limit with reference to US FDA 21 CFR 177.2600.

Test Item(s)	M06			
Parameter	Unit	Result	Detection limit	Permissible limit
Total Extractives: First 7 hours – Distilled Water (Reflux temperature)	mg/in ²	0.45	0.1	20
Total Extractives: Succeeding 2 hours – Distilled Water (Reflux temperature)	mg/in ²	0.2	0.1	1
Total Extractives: First 7 hours – Hexane (Reflux temperature)	mg/in ²	13.0	0.1	175
Total Extractives: Succeeding 2 hours – Hexane (Reflux temperature)	mg/in ²	3.8	0.1	4
Conclusion	--	PASS	--	--

Note / Key:

"<" = Less than

U. S. = United States

% = weight by weight percentage

mg/in² = miligram(s) per square inches

deg. C = degree Celsius (°C)

III. TOTAL EXTRACTIVES IN FOOD SLIMULANTS- US FDA 21 CFR 177.1655

Test method and limit with reference to US FDA 21 CFR 177.1655.

Test Item(s)	M05			
Parameter	Unit	Result(s)	Detection limit	Permissible limit
Total Extractives in Heptane (Reflux temperature for 6 hours)	mg/in ²	< 0.025	0.025	0.05
Total Extractives in Distilled water (Reflux temperature for 6 hours)	mg/in ²	< 0.025	0.025	0.05
Conclusion	--	PASS	--	--

Note / Key:

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U. S. = United States

% = weight by weight percentage

mg/in² = miligram(s) per square inches

deg. C = degree Celsius (°C)

*** END OF THE REPORT ***