Test Report

Date : 2024-04-10 **Page 1 of 4**
No. : DP24040129

Applicant : Shenzhen Kean Silicone Product Co.,Ltd
#52 Xinhe Rd, Shangmugu Community,Pinghu, Longgang
Shenzhen,guangdong province China. 518111

Description of Samples : One kind of submitted sample(s) said to be :
Item name: 2 in 1 feeding bottle
(see the attached photo)
Style/Item No.:TB21
Age Grading for Testing:0~36 months

Date Samples Received : 2024-04-03

Date Tested : 2024-04-03 to 2024-04-09

Test Requested and Conclusion(s):

No.	Standard and Requirement	Conclusion(s)
1	California Proposition 65 - Bisphenol A content	Pass
2	Rubber articles intended for repeated use – FDA 21 CFR 177.2600 - Total extractives in distilled water - Total extractives in n-hexane	Pass
3	Olefin polymers – FDA 21 CFR 177.1520 - Density - Extractable fraction in n-hexane - Soluble fraction in xylene	Pass

Yan Liang, Sky
Authorized Signatory

STC (Guangdong) Company Limited
No.68, Fumin South Road, Dalang, Dongguan, Guangdong, China Zip Code: 523770
Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : gdstc@stc.group Website : www.gdstc.group
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Sample description

Silicone materials

(1) Transparent brown silicone
(2) Transparent brown PP

Test Results:

1. **US California Proposition 65-Bisphenol A Contents***

Method used and Determined by: Solvent extraction, Analysis were performed by High performance Liquid Chromatograph-Mass Spectrometer (LC-MS MS).

Elements	Result(s)(mg/kg)		Limit
	(1)	(2)	
Bisphenol A	ND	ND	Not detected

Note(s): (1) ND= Not detected(Below MDL)
(2) Method detection limit(MDL)=0.1 mg/kg

*= The test item was not accredited by CNAS.

2. **RUBBER ARTICLES INTENDED FOR REPEATED USE – FDA 21 CFR 177.2600**

Method Used: Ref. 21 CFR 177.2600
- Total extractives in distilled water at reflux temperature
- Total extractives in n-hexane at reflux temperature

Test Item(s)	Unit	Result(s)	Limit
		(1)	
- Total extractives in distilled water at reflux temperature for first 7 hours	mg/in^2	0.8	20
- Total extractives in n-hexane at reflux temperature for first 7 hours	mg/in^2	13.6	175
- Total extractives in distilled water at reflux temperature for additional 2 hours	mg/in^2	ND	1
- Total extractives in n-hexane at reflux temperature for additional 2 hours	mg/in^2	0.7	4
Conclusion	-	Pass	-

Note(s): - ND = Not Detected
- mg/in^2 = milligram per square inch
- Method detected limit: 0.1 mg/in^2

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3. OLEFIN POLYMERS – FDA 21 CFR 177.1520

Method Used: Ref. 21 CFR 177.1520
- Density
- Extractable fraction in n-hexane
- Soluble fraction in xylene

Test Item(s)	Unit	Result(s) (2)	Limit*
- Density	g/cm^3	0.8994	0.85-1.00
- Extractable fraction in n-hexane at 50°C for 2 hours	%(w/w)	0.6	5.5
- Soluble fraction in xylene at reflux temperature for 2 hours and stand for 1 hour	%(w/w)	6.5	30
Conclusion	-	Pass	-

Note(s): - ND = Not Detected
- Method detected limit: specific gravity 0.001 g/cm^3; extractable fraction 0.1 %
- g/cm^3 denotes gram per centimeter cube

Remark(s): - * Limit quoted from 21 CFR 177.1520 for olefin polymers described in 3.1a

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Appendix for Photos of the Submitted Sample(s)



******* End of Test Report *******

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Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : gdstc@stc.group Website : www.gdstc.group
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