

Test Report No.T52110290981TC

Date: AUG 25, 2021

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HESHAN BAKE RUBBER & PLASTIC PRODUCTS FACTORY NO.27, SECOND DISTRICT, SANLIAN DEVELOPMENT ZONE. GULAO TOWN.HESHAN CITY.GUANGDONG PROVINCE.CHINA

The following samples were submitted and identified by/on behalf of the client as:

RUBBER DOG TOY

Item No.	: BKF205
Country of Origin	: CHINA
Country of Destination	: UNITED STATES

Sample Receiving Date	: AUG 13, 2021
Further Information Date	: AUG 25, 2021
Testing Period	: AUG 13, 2021 TO AUG 25, 2021

Test Requested		Conclusion
1.	The United State Code of Federal Regulations 21 CFR 177.2600 (FDA) - extractives in distilled water and n-hexane	
	(Selected test items as specified by the applicant, please refer to test result page(s) for details)	PASS

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

Signed for and on behalf of SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch Testing Center

Qu Ping, Kiky Dept. Manager





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Results:

1. FDA 21 CFR 177.2600 - Rubber

Method: With reference to 21 CFR 177.2600

Test Item(s)	1	Permissible Limit (mg/inch ²)
Alias No.	1	
Tracing No.	1	
1. Total Extractives in Distilled Water at Reflux Temperature:		
- The First 7 Hours of Extraction (mg/inch ²)	0.6	20
- The Succeeding 2 Hours of Extraction (mg/inch ²)	< 0.1	1
2. Total Extractives in n-hexane at Reflux Temperature:		
- The First 7 Hours of Extraction (mg/inch ²)	27.7	175

Specimen Description:

- 1. Orange soft plastic (Dog toy)
- Note: mg/inch² = milligram per square inch
 - < = less than

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Remark 2: The statement of conformity has considered the decision rule based on the Guarded acceptance (8.3.2 of ISO/IEC GUIDE 98-4:2012). When the measured value falls within the guard band, only the test data and measurement uncertainty will be reported. The guard band is equal to the expanded measurement uncertainty with a 95% coverage probability(k=2), w = U₉₅. The Probability of False Accept and the Probability of False Reject of the decision rule are 2.5%.

For Upper Tolerance Limit (T_{U}) :

Pass - when the measurement result is below $T_{U}\text{-}U_{95}$

Fail - when the measurement result is above T_U+U_{95}

Inconclusive - when the measurement result is falling in guard band $[\,T_U - U_{95},\,T_U + U_{95}\,]$

For Lower Tolerance Limit (TL):

Pass - when the measurement result is above $T_L + U_{\mbox{\scriptsize 95}}$

Fail - when the measurement result is below T_L-U_{95}

Inconclusive - when the measurement result is falling in guard band $[T_L-U_{95}, T_L+U_{95}]$



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Sample Photo:



SGS authenticate the photo on original report only

*** End of Report ***



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