



## Test Report

No.T52110242050TC

Date: MAR 29, 2021

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HESHAN BAKE RUBBER & PLASTIC  
PRODUCTS FACTORY  
SANLIAN INDUSTRIAL ZONE.GULAO TOWN.HESHAN  
CITY.GUANGDONG PROVINCE.CHINA

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

E-TPU

Item No. : BKI158/BKI159/BKI212/BKI214

Country of Destination : UNITED STATES

\*\*\*\*\*

Sample Receiving Date : MAR 23, 2021

Testing Period : MAR 23, 2021 TO MAR 28, 2021

Test Requested	Conclusion
1. The United State Code of Federal Regulations 21 CFR 177.2600 (FDA) - extractives in distilled water	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 <sup>2</sup> )
Alias No.	1	--
Tracing No.	1	--
1. Total Extractives in Distilled Water at Reflux Temperature:	--	--
- The First 7 Hours of Extraction (mg/inch <sup>2</sup> )	< 0.1	20
- The Succeeding 2 Hours of Extraction (mg/inch <sup>2</sup> )	< 0.1	1

**Specimen Description:**

1. White w/ multi-color soft plastic (Body)

Note: - mg/inch<sup>2</sup> = 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 ( $k=2$ ),  $w = U_{95}$ . 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  $T_U - U_{95}$ 

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 ( $T_L$ ):

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

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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SGS authenticate the photo on original report only

\*\*\* End of Report \*\*\*