

Tests According to Standards for Apparatus and Container-Packages Made of Rubber

(Notification No. 370, issued by the Ministry of Health and Welfare of Japan, dated in 1959)

Final revision by Notification No.380 (2020)

(1) Rubber utensils (except nursing utensils) and containers /packagings

Test Item	Standard	Elution condition (Elution rate : 2 mL/cm ²)		Unit Price (JPY)	Required amounts of test samples
		Condition for use ≤100℃	Condition for use >100℃		
Material Test					
Cadmium and Lead	Not exceed the absorbance of the standard solution (each 100 μg/g or less)			*1 Silicone rubber:15000 Other rubber:11000	3 g
2-Mercaptoimidazoline *2	Peak of 2-Mercaptoimidazoline must not be found			12000	3 g
ElutionTest					
Phenol	Not exceed the absorbance of the standard solution (5 μg/mL or less)	Water 60℃, 30 min	Water 95℃, 30 min	5500	According to Evaporation residue condition, minimum 1 sheet for 3 conditons (1sheet : 210mm × 297mm, A4 size)
Formaldehyde	Not darker in color than the contrast solution (about 4 μg/mL or less)			6000	
Zinc	Not exceed the absorbance of the standard solution (15 μg/mL or less)	4% acetic acid 60℃, 30 min	4% acetic acid 95℃, 30 min	5500	
Heavy metals	Not darker in color than the control solution (1 μg/mL or less)			3000	
Evaporation residue *3	Fats, oils and fatty foods, Alcoholic beverages	60 μg/mL or less	20 % ethanol 60℃, 30 min		4500
	pH over 5		Water 60℃, 30 min	Water 95℃, 30 min	4500
	pH 5 or less		4% acetic acid 60℃, 30 min	4% acetic acid 95℃, 30 min	4500

*1: To confirm whether it is silicone rubber or not, the identification test is available; JPY6000

*2: Applied to only rubber products that contain chlorine. Qualitative test of chlorine : JPY3000

*3: For implements, use water as leaching solution. For containers and packaging, leaching solutions must be chosen according to the type of foods.

(2) Nursing utensils

Test Item	Standard	Elution conditon (Elution rate : 20 mL/g)	Unit Price (JPY)	Required amounts of test samples	
Material Test					
Cadmium and Lead	Not exceed the absorbance of the standard solution (each 10 µg/g or less)		*1 Silicone rubber:15000 Other rubber:11000	more than 50 g and more than 5 pieces	
ElutionTest					
Phenol	Not exceed the absorbance of the standard solution (5 µg/mL or less)	Water 40℃, 24 hours	5500		
Formaldehyde	Not darker in color than the contrast solution (about 4 µg/mL or less)		6000		
Zinc	Not exceed the absorbance of the standard solution (1 µg/mL or less)		5500		
Heavy metals	Not darker in color than the control solution (1 µg/mL or less)	4% acetic acid 40℃, 24 hours	3000		
Evaporation residue	40 µg/mL or less	Water 40℃, 24 hours	4500		

*1: To confirm whether it is silicone rubber or not, the identification test is available; JPY6000