

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°C | Condition for use > 100°C | | |
| 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°C, 30 min | Water 95°C, 30 min | 5500 | According to Evaporation residue condition, minimum 1 sheet for 3 conditons |
| 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°C, 30 min | 4% acetic acid 95°C, 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 | 20 % ethanol 60°C, 30 min | | 4500 | (1sheet : 210mm x 297mm, A4 size) |
| | pH over 5 | Water 60°C, 30 min | Water 95°C, 30 min | 4500 | |
| | pH 5 or less | 4% acetic acid 60°C, 30 min | 4% acetic acid 95°C, 30 min | 4500 | |

*1: To confirm whether it is silicone rubber or not, the identification test is available; JPY4500

*2: Applied to only rubber products that contain chlorine. Qualitative test of chlorine : JPY2000

*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 condition (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°C, 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°C, 24 hours | | 3000 | | |
| Evaporation residue | 40 µg/mL or less | Water 40°C, 24 hours | | 4500 | | |

*1: To confirm whether it is silicone rubber or not, the identification test is available; JPY4500