

Establishment of Specifications and Standards for Apparatus and Containers/Packages made of Polylactic Acid Resins

Purpose

This activity is to develop specifications and standards for food apparatus and containers/packages made of synthetic resins and ensure the safety of these products.

Synthetic resins whose main component is polylactic acid (PLA) are already in commercial use in Japan as eating utensils. In Europe and the United States, these resins are used for a wider variety of purposes including as throw-away eating utensil and as food containers. They are expected to be widely used in Japan as well. Given such situation, the Ministry of Health, Labour and Welfare has decided to newly establish specifications and standards for PLA resin apparatus, containers, and packages for foods.

The Food Sanitation Law regulates apparatus, containers, and packages for foods. They shall meet specifications and standards under the law.

Outline of establishment

The law specifies two types of specifications—general specifications and individual specifications—in Item 2 “Apparatus and Containers/Packages Made of Synthetic Resins” in Section D “Specifications for Apparatus and Containers/Packages According to Material” in Part 3 “Apparatus and Containers/Packages” in the Specifications and Standards for Food and Food Additives (specified in Ministry of Health and Welfare Notification No. 370 in 1959). Individual specifications will be newly established for the new category “PLA resin apparatus and containers/packages.” Also, some requirements will be established in Section F “Standards for Manufacturing.”

In step with the establishment of the specifications, Sections B and C of Part 3 will be revised. In Section B the test method of total lactic acid will be newly established as a monomer test and in Section C some reagents and standards solutions will be added.

After the implementation of the revision, the PLA resins will be subjected to the individual specifications and the existing general specifications for synthetic resins based on the Food Sanitation Law. See the attachment 5-2 for details.

Attachment 1

Part 3 Apparatus and Containers/Packages

B. General Tests

8. Monomer tests

Total lactic acid

(1) Identification test

Measure 1 ml each of the sample solution and lactic standard solution, add 100 μ l of 0.2 mol/l sodium hydroxide, and stopper. Allow them to stand for 15 minutes with occasional shaking while maintaining at 60°C. After cool, add 100 μ l of 0.2 mol/l phosphoric acid to each. Using a 100 μ l portion for each solution, perform liquid chromatography according to the conditions given below, and compare the peak detection time in the chromatogram of the test solution to the peak detection time in the chromatogram of the lactic acid standard solution.

Operating conditions

Column: A stainless steel with an internal diameter of 4.6 mm and a length of 250 mm

Column packing material: Octadecylsilanized silica gel

Column temperature: 40°C

Detector: An ultraviolet spectrophotometric detector (detection wavelength: 210 nm)

Mobil phase: A mixture of phosphoric acid, acetonitrile, and water (0.1:1:99)

Adjust the flow rate so that lactic acid flows out in about 5 minutes.

(2) Quantitative test

Perform the following test when in the qualification test (1) the peak detection time of the sample solution matches the peak detection time of the standard solution.

Using the results obtained under the conditions given in the qualification test (1), measure the peak area of lactic acid in the sample solution. The peak area should not be greater than the peak area of the lactic acid standard solution.

C. Reagents and Solutions

Reagents

L-Lithium lactate $\text{CH}_3\text{CH}(\text{OH})\text{COOLi}$ Contains at least 97% of lithium lactate ($\text{CH}_3\text{CH}(\text{OH})\text{COOLi}$).

Phosphoric acid H_3PO_4 [K9005, Special grade]

Solutions

0.2 mol/l sodium hydroxide Dissolve 8.0 g of sodium hydroxide in water, and add water to make 1,000 ml.

0.2 mol/l phosphoric acid Add water to 14 ml of phosphoric acid to make 1,000 ml.

Standard solution

Lactic acid standard solution Add water to 1.07 g of L-lithium lactate, exactly weighed, to make 1,000 ml. Measure 3 ml of this solution, and add water to make 1,00 ml. One ml of this solution contains 30 µg of lactic acid.

D. Material Specifications

<Synthetic resins>

Individual specifications

Item 13. PLA resins

Apparatus and containers/packages made of PLA resins shall pass the following tests.

a. Migration tests

i. Total lactic acid (Not more than 30 µg/ml)

The specification for total lactic acid shall be met when the test is performed as directed in the monomer tests, using water as a stimulant. The total lactic acid in the sample solution is not more than 30 µg/ml, if the product meets the requirement.

ii. Residue on evaporation (Not more than 30 µg/ml)

The residue shall be not more than 30 µg/ml, when test is performed as directed in the residue on evaporation test.

F. Standards for Manufacturing

PLA containing more than 6% (weigh) D-lactic acid shall not be used as an ingredient of apparatus or containers/packages which are expected to be used at a temperature over 40°C. However, this requirement does not apply to products which are used for up to 2 hours at a temperature of more than 40°C and not more than 66°C or which are used for up to 30 minutes at a temperature of more than 66°C and not more than 100°C.