



## ORYZA OIL & FAT CHEMICAL CO.,LTD.

1 Aza Numata Kitagata Kitagata-cho Ichinomiya-city, Aichi-prefecture 493-8001 JAPAN  
 Phone:+81-586-86-5141 Facsimile:+81-586-86-6191  
 URL/http://www.oryza.co.jp/ E-mail:info@oryza.co.jp

### PRODUCT STANDARD

PRODUCT NAME: **JAPANESE BUTTERBUR EXTRACT-P** (FOOD)

This product is extracted with aqueous ethanol from Japanese butterbur, the stem and the leaves of *Petasites japonicus* (Compositae).

**Appearance**

Slight yellowish powder with slight unique aroma.

**Certification Test**

**(1)Fukinolic acid**

After a small amount of methanol (HPLC grade) is added to 250mg of this product in a 10mL volume flask, and the flask is treated with ultra-sonic wave for 10 minutes. The solution is filtered through a 0.45  $\mu$  m PTFE filter after addition of methanol (HPLC grade) to adequate volume. For preparation of standard solution, methanol (HPLC grade) is added to fukinolic acid, and the concentration is prepared 0.1mg/mL (standard solution). HPLC analysis is performed according to the following conditions for 5  $\mu$  L of test solution and standard solution. The peak of fukinolic acid is found in the HPLC chromatogram of test solution.

<HPLC condition >

Column : capcellpak C18 (4.6 mm  $\phi$   $\times$  250 mm)  
 Mobile phase : Solvent A = Citric acid solution  
 (citric acid monohydrate 2.1g $\rightarrow$ 1L)  
 Solvent B = Methanol

Condition of gradient

Time(min)	0	19	25	35	50	60	61	70
Mobile phase	100% A	100% A	80%A 20%B	80%A 20%B	60%A 40%B	60%A 40%B	100% B	100% B

Flow rate : 1.0mL/min

Detector : UV 324 nm

Column temperature : 30°C

**(2)Fukinone**

This product (2.0g) in a centrifugation tube is suspended in purified water (10mL), and treated with ultra-sonic wave for 1 minute. Ethyl acetate (10mL) is added to the suspension, and the tube is shaken for 3 minutes. Then the tube is centrifuged (room temperature, 3000 rpm, 10minutes), and an ethyl acetate layer is collected (repeat this procedure three times) . The collected ethyl acetate layer is evaporated and is dissolved in 20% acetonitrile (3mL), and is filtered through a Sep-Pak C18 cartridge. Then, the cartridge is washed with 70% acetonitrile (7mL) and is eluted with absolute acetonitrile (5mL). This solution is adjusted to 10mL, and filtered through a 0.45  $\mu$  m PTFE filter (test solution). For preparation of standard solution, acetonitrile is added to fukinone, and the concentration is prepared 0.1mg/mL (standard solution). HPLC analysis is performed according to the following conditions for 5  $\mu$  L of test solution and standard solution. The peak of fukinone is found in the HPLC chromatogram of test solution.



## ORYZA OIL & FAT CHEMICAL CO.,LTD.

1 Aza Numata Kitagata Kitagata-cho Ichinomiya-city, Aichi-prefecture 493-8001 JAPAN  
 Phone:+81-586-86-5141 Facsimile:+81-586-86-6191  
 URL/http://www.oryza.co.jp/ E-mail:info@oryza.co.jp

### < HPLC condition >

Column : Shim-pack CLC-ODS (6.0 mm  $\phi$   $\times$  150 mm)  
 Mobile phase : acetonitrile : water = 8 : 2  
 Flow rate : 1.0mL/min  
 Detector : UV 254 nm  
 Column temperature : 30°C

<b><u>Total polyphenols</u></b>	Min. 1.0 %	(Folin-Denis method)
<b><u>Total terpenoids</u></b> [In non-excipient from(JAPANESE BUTTERBUR EXTRACT) ]	Min. 300 $\mu$ l/100g	(Japanese Pharmacopoeia, Essential oil content) (Theoretical value in JAPANESE BUTTERBUR EXTRACT-P : Min.60 $\mu$ L/100g)
<b><u>Loss on Drying</u></b>	Max. 10.0 %	(Analysis for Hygienic Chemists, 1g, 105 °C, 2 hr)
<b><u>Purity Test</u></b>		
(1)Heavy Metals (as Pb)	Max. 10 ppm	(Sodium Sulfide Colorimetric Method)
(2)Arsenic (as As <sub>2</sub> O <sub>3</sub> )	Max. 1 ppm	(Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B)
<b><u>Standard Plate Counts</u></b>	Max. 3 $\times$ 10 <sup>3</sup> cfu/g	(Analysis for Hygienic Chemists)
<b><u>Moulds and Yeasts</u></b>	Max. 1 $\times$ 10 <sup>3</sup> cfu/g	(Analysis for Hygienic Chemists)
<b><u>Coliforms</u></b>	Negative	(Analysis for Hygienic Chemists)

<b><u>Composition</u></b>	<u>Ingredient</u>	<u>Content</u>
	Maltodextrin	80 %
	Japanese Butterbur Extract	20 %
	Total	100 %

### **Expiry date**

2 years from date of manufacturing.

### **Storage**

Store it in a cool, dry, ventilated area with desiccant.

Keep it away from high temperature and sunlight, and store it in a closed container.

Established Date	June 5, 2004
Revised Date	June 3, 2019
Specification No.	G-903EN