

ORYZA OIL & FAT CHEMICAL CO., LTD.

ORYZA STEROL

Anti-Cholesterol Ingredient
Cosmetic Ingredient

- **ORYZA STEROL-P**
- **ORYZA STEROL-L**
- **ORYZA STEROL-PC** (Cosmetic)
- **ORYZA STEROL-LC** (Cosmetic)



ORYZA OIL & FAT CHEMICAL CO., LTD.

ver. 3.2 YF

ORYZA STEROL

Anti-Cholesterol Ingredient

1. Introduction

Rice (*Oryza sativa*) have been widely grown in the Southeast Asia, not only as a chief crop but also as acts an integral part of traditional culture and lifestyle of some Asian countries.

In recent years, much attention have been focused on rice bran and rice germ, which are discharged in the process of the polished rice production, because of it contains many unique bioactive compounds.

In the course of our investigation on rice bran and rice germ for a long time, some products were developed by utilizing functional compounds containing in it, and have been used as medicines, cosmetics, health foods, and food additives.

More recently, sterols were extracted from rice bran and rice germ, and produced to nutritional and cosmeceutical supplement by ORYZA OIL & FAT CHEMICAL CO., LTD.

2. What is a sterol?

A “steroid” is the generic term for a compound consisting of a cyclopentanoperhydro-phenanthrene nucleus ($C_{17}H_{28}$). When the compound has a hydroxyl group, particularly at the position of the third carbon atom, and contains 27 to 30 carbon atoms, it is called a “sterol”. Sterols are distributed in a wide variety of cells as free sterols, fatty acid esters and sterol glycosides.

Cholesterol, a 27-C sterol, is mainly found in animal cells, whereas β -sitosterol, stigmasterol and campesterol are well-known phytosterols abundantly distributed in plants (Figure 1).

Among various vegetable oils, rice oil contains the highest concentration of phytosterols, which is approximately twice as much as that of rape oil and 20 times greater than that of palm oil (Figure 2)¹⁾. Considerable worldwide attention has recently been focussed on the safety of genetically modified produce including soybeans, corn, oilseed rape and cottonseeds. On the other hand, food labeling is required or encouraged to identify food items containing potential allergens derived from eggs, wheat, buckwheat, peanuts, milk or soybeans. ORYZA STEROL, a rice processed product, includes neither genetically modified ingredients nor specific allergy-causing substances needing to be labeled.

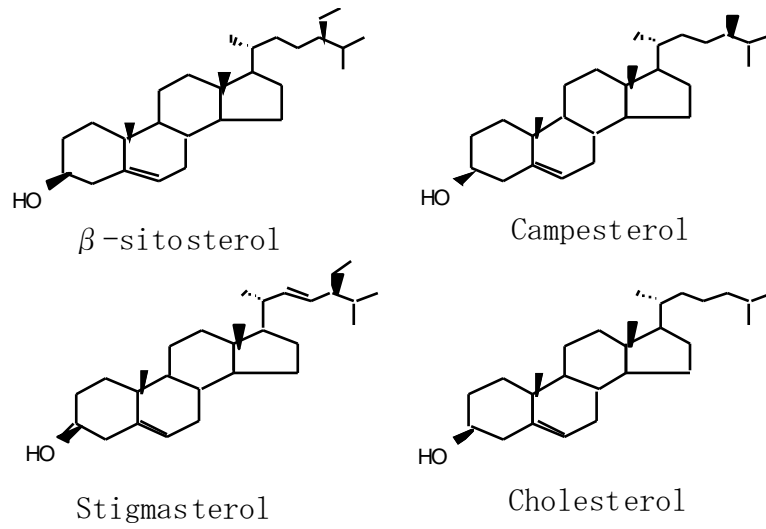


Figure 1. Structures of major phytosterols

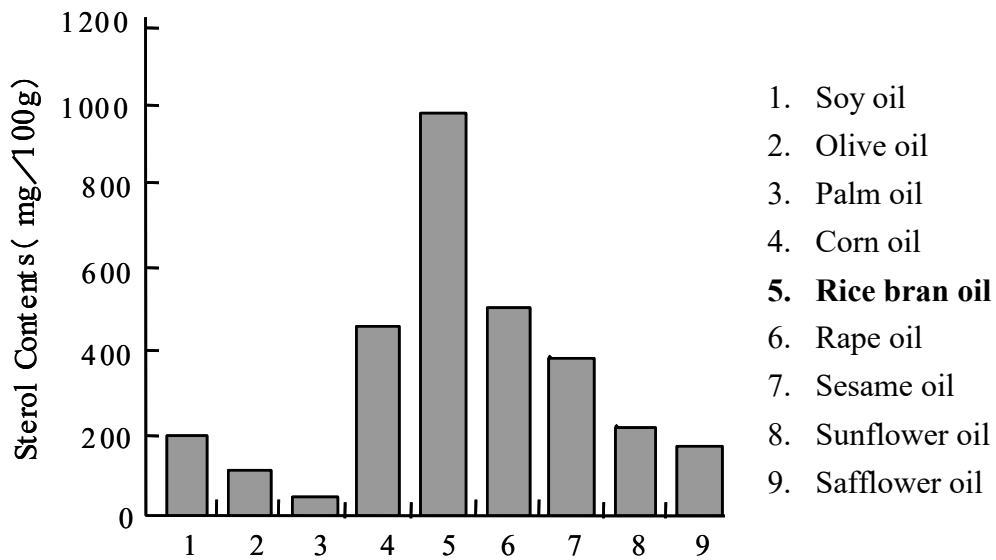


Figure 2. Contents of total sterols.

3. Cholesterol and lifestyle-related diseases

Cholesterol is an essential component in the body. However, many studies have demonstrated that excessive cholesterol, especially the accumulation of low-density lipoprotein (LDL, known as bad cholesterol), causes arteriosclerosis that is a key risk factor for cardiovascular diseases including angina pectoris, myocardial infarction, stroke and cerebral thrombosis.

Recent lifestyle changes involving excessive protein, fat and sugar consumption, stressful conditions and physical inactivity have increased the incidence of cardiovascular disease, which is now the leading cause of death in the world, as well as in Japan.

In consideration of this situation, the Japan Arteriosclerosis Society has provided guidelines to maintain blood cholesterol levels under control. They recommend improving the lifestyle through diet and exercise as the first step to prevent and treat hypercholesterolemia.

4. Potential function of ORYZA STEROL

Phytosterol is found in various plant cells as a type of lipid. Extensive research has clarified the physiological functions of phytosterol. These include a cholesterol-lowering effect, the improvement of dysuria in benign prostatic hyperplasia, an inhibitory effect against cancer proliferation and inflammation-suppressing activity.

4-1 The cholesterol-lowering effect

It has been recognized that phytosterol lowers blood cholesterol levels as confirmed in clinical trials.

A clinical investigation into phytosterol was conducted by Miettinen et al., in which hypercholesterolemic patients consumed margarine containing sitostanol ester for one year. As a result, the daily consumption of 1.8 or 2.6 g of sitostanol ester reduced total blood cholesterol and LDL levels by 10 to 14%²⁾.

In 1999, Goto et al. examined the cholesterol-lowering effect of diacylglycerol containing phytosterol in 45 volunteers whose total blood cholesterol levels exceeded 200 mg/dl. After a four-week experimental period, a significant reduction in total blood cholesterol and LDL levels was observed in the group consuming 400 mg/day of phytosterol (including 158 mg of β -sitosterol) as compared to the control group. They concluded that the effect was essentially provided by phytosterol (β -sitosterol) (Figure 3)³.

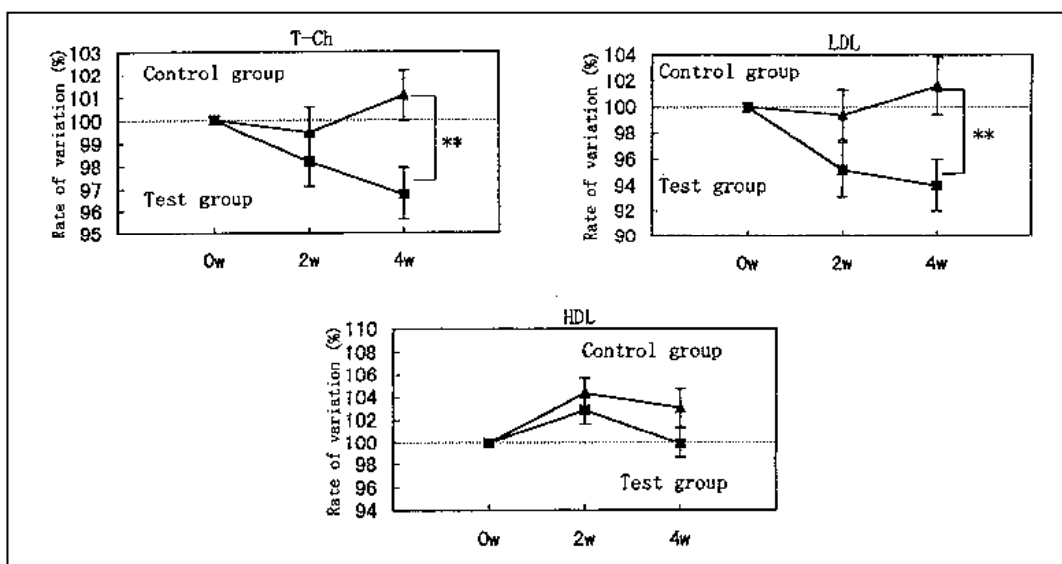


Figure 3. Cholesterol-lowering effect by phytosterol

The mechanisms by which phytosterol reduces blood cholesterol levels have been explained as follows; along with cholesterol, phytosterol, especially β -sitosterol, is dissolved by bile acid micelles secreted from the gallbladder. Since the capacity of bile acid micelles is limited, the presence of β -sitosterol reduces cholesterol solubility and its transportation to the blood, resulting in lowered blood cholesterol levels.

4-2 Improvement of dysuria in benign prostatic hyperplasia

Besides lowering blood cholesterol levels, phytosterol improves symptoms related to benign prostatic hyperplasia as observed in several clinical trials.

In 1995, Berges et al. carried out a clinical trial in which 200 patients with benign prostatic hyperplasia were treated with 20 mg of β -sitosterol three times per day for six months. The treatment was evaluated using the international prostate symptom score

(IPSS) that summarized parameters indicating urinary flow and volume, residual urine volume and prostate volume. As compared to the control, those treated with sitosterol showed a marked improvement in symptoms associated with benign prostatic hyperplasia⁴⁾.

Along with these functions, phytosterol has an inhibitory effect on cancer proliferation as well as on inflammatory reactions in autoimmune disease. Based on numerous clinical trials, phytosterol is now used extensively as an ingredient for food products, functional foods, dietary supplements, food additives and cosmetics in Japan as well as in Europe and the United States.

Reference:

- 1) *Report of JAS Grading result for Plant Oil*, Jan-Dec, (1994)
- 2) Miettinen TA, Puska P et al., *The New England Journal of Medicine*, **16**, 1308 (1995)
- 3) N. Goto, *Journal of Japan Oil Chemists' society*, **48**, 47-52 (1999)
- 4) P R Berges, J Windeler et al., *The Lancet* **345**, 1529-1532 (1995)

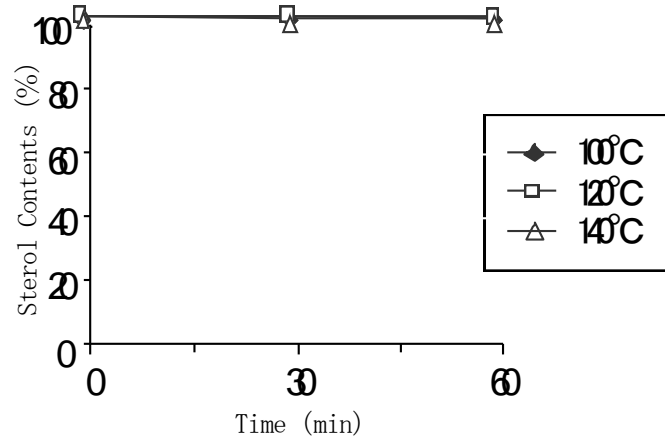
5. Composition of ORYZA STEROL

Just for reference, composition of a sample is showing.

Brassicasterol	5.90 %
Campesterol	21.92 %
Stigmasterol	22.26 %
β -sitosterol	49.92 %
Total sterol	100.00 %

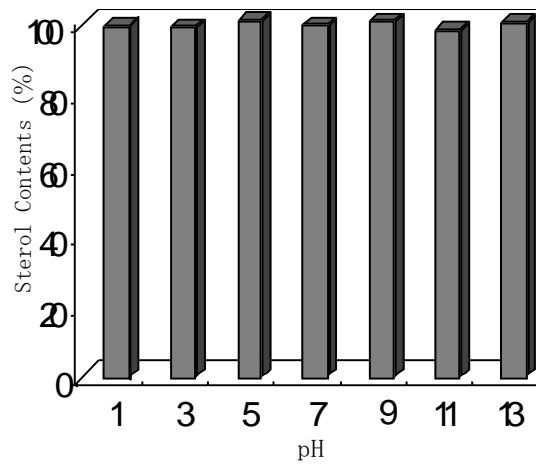
6. Thermal Resistance

The Pyrolysis of ORYZA STEROL does not occur at a normal food processing temperature for 60 minutes.



7. pH Stability

ORYZA STEROL remains stable especially at neutral to acid field of pH.



※ The sterol concentration in 95% ethanol solution (pH 6.8 unregulated) was set 100%

8. Daily dosage of ORYZA STEROL-P

It is recommended to take about 500mg/day of **ORYZA STEROL-P**.

9. Practical applications of ORYZA STEROL

Applications	Examples
Confectionery	Candies, Gum, Cookies, Pudding, Jelly, Yogurt, Chocolate, etc...
Cosmetics	Base cosmetics (Lotion, Milk, Cream, and so on) Body cosmetics (Body lotion, Body cream, and so on) Cleansing cosmetics (Soap, and so on) Makeup cosmetics (Lipstick, Foundation, and so on)
Others	Functional foods, Nutraceutical foods, and Health foods

10. Packaging

ORYZA STEROL-P (powder type for foods)

ORYZA STEROL-PC (powder type for cosmetics)

5kg Interior packaging: a double layered plastic bag
Exterior packaging: 18L tin and cardboard box

ORYZA STEROL-L (liquid type for foods)

ORYZA STEROL-LC (liquid type for cosmetics)

5kg Interior packaging: cubic polyethylene container
Exterior packaging: cardboard box

11. Storing method

Store in cool, dry place. Avoid humidity.

12. Expression of ORYZA STEROL

ORYZA STEROL-P, ORYZA STEROL-L

Rice Sterol

Plant Sterol

Phytosterol

※Please refer to your nation's standard.

ORYZA STEROL-PC

ORYZA STEROL-PC is recommended for cosmetics

INCI name: Oryza Sativa (Rice) Bran Sterol

ORYZA STEROL-LC

ORYZA STEROL-LC is recommended for cosmetics

INCI name: Glycerin (and) Water (and) Caprylic/Capric Triglyceride (and)
Polyglyceryl-6 Laurate (and) Oryza Sativa (Rice) Bran Sterol (and)
Lecithin

PRODUCT STANDARD

PRODUCT NAME

ORYZA STEROL-P

(FOOD)

This product is extracted with ethanol from the rice bran and the rice germ of *Oryza sativa* Linne (Gramineae) and subsequently refined. It includes more than 90.0 % of sterols.

<u>Appearance</u>	It is white or yellowish colored powder. It has no smell.	
<u>Content of Sterols</u>	Min. 90.0 %	(GC)
<u>Loss on Drying</u>	Max. 3.0 %	(Analysis for Hygienic Chemists, 1g, 105°C, 2h)
<u>Purity Test</u>		
(1) Heavy Metals Additives)	Max. 10 ppm	(The Japanese Standards for Food Additives)
(2) Arsenic	Max. 1 ppm	(Standard Methods of Analysis in Food Safety Regulation)
<u>Standard Plate Counts</u>	Max. 1×10^3 cfu/g	(Analysis for Hygienic Chemists)
<u>Moulds and Yeasts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Coliforms</u>	Negative	(Analysis for Hygienic Chemists)
<u>Composition</u>	<u>Ingredient</u>	<u>Content</u>
	Rice sterol	100 %

PRODUCT STANDARD

PRODUCT NAME

ORYZA STEROL-L

(FOOD)

This product is emulsified liquid of sterol extracted from the rice bran and the rice germ of *Oryza sativa* Linne (Gramineae). It includes more than 3.0 % of sterols.

<u>Appearance</u>	It is yellowish liquid with slightly unique smell.	
<u>Content of Sterols</u>	Min. 3.0 %	(GC)
<u>Purity Test</u>		
(1) Heavy Metals	Max. 10 ppm (The Japanese Standards for Food Additives)	
(2) Arsenic	Max. 1 ppm (Standard Methods of Analysis in Food Safety Regulation)	
<u>Standard Plate Counts</u>	Max. 1×10^3 cfu/g	(Analysis for Hygienic Chemists)
<u>Moulds and Yeasts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Coliforms</u>	Negative	(Analysis for Hygienic Chemists)

<u>Composition</u>	<u>Ingredients</u>	<u>Contents</u>
	Rice sterol	3 %
	Glycerin	37 %
	Triglyceride	15 %
	Glycerin ester of fatty acid	6 %
	Lecithin	3 %
	Purified water	36 %
	Total	100 %

PRODUCT STANDARD

PRODUCT NAME

ORYZA STEROL-PC

(COSMETIC)

This product is extracted with ethanol from the rice bran and the rice germ of *Oryza sativa* Linne (Gramineae) and subsequently refined. It includes more than 90.0 % of sterols.

<u>Appearance</u>	It is white or yellowish colored powder. It has no smell.	
<u>Content of Sterol</u>	Min. 90.0 %	(GC)
<u>Loss on Drying</u>	Max. 3.0 %	(1 g, 105 °C, 1 h)
<u>Purity Test</u>		
(1) Heavy Metals	Max. 10 ppm	
(2) Arsenic	Max. 1 ppm	
<u>Standard Plate Counts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Moulds and Yeasts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Coliforms</u>	Negative	(Analysis for Hygienic Chemists)
<u>Composition</u>	<u>Ingredient</u>	<u>Content</u>
	Oryza Sativa (Rice) Bran Sterol	100 %

We referred to the experiment methods of the Japanese Standards of Cosmetic Ingredients.

PRODUCT STANDARD

PRODUCT NAME

ORYZA STEROL-LC

(COSMETIC)

This product is emulsified liquid of sterol extracted from the rice bran and the rice germ of *Oryza sativa* Linne (Gramineae). It includes more than 3.0 % of sterols.

<u>Appearance</u>	It is yellowish liquid with slightly unique smell.	
<u>Content of Sterols</u>	Min. 3.0 %	(GC)
<u>Purity Test</u>		
(1) Heavy Metals	Max. 10 ppm	
(2) Arsenic	Max. 1 ppm	
<u>Standard Plate Counts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Moulds and Yeasts</u>	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
<u>Coliforms</u>	Negative	(Analysis for Hygienic Chemists)
<u>Composition</u>	<u>Ingredients</u>	<u>Contents</u>
	Glycerin	37 %
	Water	36 %
	Caprylic/Capric Triglyceride	15 %
	Polyglyceryl-6 Laurate	6 %
	Oryza Sativa (Rice) Bran Sterol	3 %
	<u>Lecithin</u>	<u>3 %</u>
	Total	100 %

We referred to the experiment methods of the Japanese Standards of Cosmetic Ingredients.

ORYZA OIL & FAT CHEMICAL CO., LTD. striving for the development of the new functional food materials to promote health and general well-being.

From product planning to OEM - For any additional information or assistance, please contact :

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