ORYZA STEROL

Anti-Cholesterol Ingredient
Cosmetic Ingredient

■ ORYZA STEROL–P
■ ORYZA STEROL–L
■ ORYZA STEROL–PC (Cosmetic)
■ ORYZA STEROL–LC (Cosmetic)
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). 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

- β-sitosterol
- Stigmasterol
- Campesterol
- Cholesterol

Figure 2. Contents of total sterols.

1. Soy oil
2. Olive oil
3. Palm oil
4. Corn oil
5. Rice bran oil
6. Rape oil
7. Sesame oil
8. Sunflower oil
9. Safflower oil
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 animal studies and clinical trials.

Sugano et al. compared the efficacy of \( \beta \)-sitosterol and \( \beta \)-sitostanol in lowering serum cholesterol levels in rats and rabbits. They indicated that \( \beta \)-sitostanol significantly inhibited cholesterol absorption, resulting in a superior lowering of cholesterol to that of \( \beta \)-sitosterol (Figure 3)\(^2\). 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\%\(^3\).
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 4).
The mechanisms by which phytosterol reduces blood cholesterol levels have been explained as follows; along with cholesterol, phytosterol, especially \( \beta \)-sitosterol, is dissolved by bile acid micelles secreted from the gallbladder. Since the capacity of bile acid micelles is limited, the presence of \( \beta \)-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 \( \beta \)-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 hyperplasia\(^5\).

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)
5) 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.

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brassicasterol</td>
<td>5.90</td>
</tr>
<tr>
<td>Campesterol</td>
<td>21.92</td>
</tr>
<tr>
<td>Stigmasterol</td>
<td>22.26</td>
</tr>
<tr>
<td>β-sitosterol</td>
<td>49.92</td>
</tr>
<tr>
<td>Total sterol</td>
<td>100.00</td>
</tr>
</tbody>
</table>

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. Acute toxicity

Five weeks old mice were orally given ORYZA STEROL (2000mg/kg) and then fed a laboratory chow for two weeks. No toxic effects were observed, thus the LD50 (mice) is more than 2000mg/kg.

10. Practical applications of ORYZA STEROL

<table>
<thead>
<tr>
<th>Applications</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confectionery</td>
<td>Candies, Gum, Cookies, Pudding, Jelly, Yogurt, Chocolate, etc…</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>Base cosmetics (Lotion, Milk, Cream, and so on)</td>
</tr>
<tr>
<td></td>
<td>Body cosmetics (Body lotion, Body cream, and so on)</td>
</tr>
<tr>
<td></td>
<td>Cleansing cosmetics (Soap, and so on)</td>
</tr>
<tr>
<td></td>
<td>Makeup cosmetics (Lipstick, Foundation, and so on)</td>
</tr>
<tr>
<td>Others</td>
<td>Functional foods, Nutraceutical foods, and Health foods</td>
</tr>
</tbody>
</table>

11. 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

12. Storing method

Store in cool, dry place. Avoid humidity.
13. 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.

**Appearance**
It is white or yellowish colored powder.
It has no smell.

**Content of Sterols**
Min. 90.0 %
(Analysis for Hygienic Chemists)

**Loss on Drying**
Max. 3.0 %
(Analysis for Hygienic Chemists, 1g, 105°C, 2h)

**Residue on Ignition**
Max. 0.5 %
The Japanese Standards for Food Additives

**Melting Point**
131~141 °C
(The Japanese Standards for Food Additives)

**Acid Value**
Max. 0.5
(The Japanese Standards for Food Additives)

**Purity Test**
(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)

**Standard Plate Counts**
Max. $1 \times 10^3$ cfu/g
(Analysis for Hygienic Chemists)

**Moulds and Yeasts**
Max. $1 \times 10^2$ cfu/g
(Analysis for Hygienic Chemists)

**Coliforms**
Negative
(Analysis for Hygienic Chemists)

**Composition**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rice sterol</td>
<td>100 %</td>
</tr>
</tbody>
</table>
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.

**Appearance**
It is yellowish liquid with slightly unique smell.

**Content of Sterols**
Min. 3.0 %  
(GC)

**Purity Test**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Max. Limit</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Heavy Metals</td>
<td>10 ppm</td>
<td>(The Japanese Standards for Food Additives)</td>
</tr>
<tr>
<td>(2) Arsenic</td>
<td>1 ppm</td>
<td>(Standard Methods of Analysis in Food Safety Regulation)</td>
</tr>
</tbody>
</table>

**Standard Plate Counts**
Max. $1 \times 10^3$ cfu/g  
(Analysis for Hygienic Chemists)

**Moulds and Yeasts**
Max. $1 \times 10^2$ cfu/g  
(Analysis for Hygienic Chemists)

**Coliforms**
Negative  
(Analysis for Hygienic Chemists)

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rice sterol</td>
<td>3 %</td>
</tr>
<tr>
<td>Glycerin</td>
<td>37 %</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>15 %</td>
</tr>
<tr>
<td>Glycerin ester of fatty acid</td>
<td>6 %</td>
</tr>
<tr>
<td>Lecithin</td>
<td>3 %</td>
</tr>
<tr>
<td>Purified water</td>
<td>36 %</td>
</tr>
<tr>
<td>Total</td>
<td>100 %</td>
</tr>
</tbody>
</table>
ORYZA STEROL CATALOG ver. 3.0KZ

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.

**Appearance**
It is white or yellowish colored powder. It has no smell.

**Content of Sterols**
Contrast of relative retention time by gas chromatography.
- Column: 1 % SE-30 (I.D. 3.2 mm × 2 m)
- Column temperature: 240 °C
- Injector temperature: 280 °C
- Detector temperature: 280 °C
- Detector: FID.

**Content of Sterol**
Min. 90.0 % (GC)

**Loss on Drying**
Max. 3.0 % (1 g, 105 °C, 1 h)

**Residue on Ignition**
Max. 0.1 % (The second method, 1 g)

**Purity Test**
1. **Heavy Metals** Max. 10 ppm
2. **Arsenic** Max. 1 ppm

**Melting Point**
131~141 °C (The first method)

**Acid Value**
Max. 0.5 (The first method, 10 g)

**Standard Plate Counts**
Max. $1 \times 10^3$ cfu/g (Analysis for Hygienic Chemists)

**Moulds and Yeasts**
Max. $1 \times 10^2$ cfu/g (Analysis for Hygienic Chemists)

**Coliforms**
Negative (Analysis for Hygienic Chemists)

**Composition**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oryza Sativa (Rice) Bran Sterol</td>
<td>100 %</td>
</tr>
</tbody>
</table>

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.

**Appearance**

It is yellowish liquid with slightly unique smell.

**Certification Test**

(1) Contrast of relative retention time by gas chromatography.

- **Column**: 1 % SE-30 (I.D. 3.2 mm × 2 m)
- **Column temperature**: 240 °C
- **Injector temperature**: 280 °C
- **Detector temperature**: 280 °C
- **Detector**: FID.

(2) (Glycerin) 10 g of this product is dissolved in 50ml of ethanol in separating funnel. Ethanol layer is evaporated. When 0.5 g of potassium hydrogensulfate is added in residue and heated, it occurs irritating smell.

(3) (Triglyceride) When analysis is performed by gas chromatography, peaks of standard solution and sample solution show same retention time.

(4) (Lecithin) 1 g of this product, 5 g of potassium sulfate, 0.5 g copper sulfate and 20ml of sulfuric acid are heated in kjeldahl frask. After solution changes transparent blue, heat for 2 hours. After cool, 20 ml of water is added. 10ml of ammonium molybdate solution is added in 5 ml of this solution, then it occurs yellow precipitate.

**Content of Sterols**

Min. 3.0 % (GC)

**Purity Test**

(1) Heavy Metals Max. 10 ppm
(2) Arsenic Max. 1 ppm

**Standard Plate Counts**

Max. $1 \times 10^3$ cfu/g (Analysis for Hygienic Chemists)
Moulds and Yeasts | Max. $1 \times 10^2$ cfu/g | (Analysis for Hygienic Chemists)
Coliforms | Negative | (Analysis for Hygienic Chemists)

### Composition

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>37 %</td>
</tr>
<tr>
<td>Water</td>
<td>36 %</td>
</tr>
<tr>
<td>Caprylic/Capric Triglyceride</td>
<td>15 %</td>
</tr>
<tr>
<td>Polylglyceryl–6 Laurate</td>
<td>6 %</td>
</tr>
<tr>
<td>Oryza Sativa (Rice) Bran Sterol</td>
<td>3 %</td>
</tr>
<tr>
<td>Lecithin</td>
<td>3 %</td>
</tr>
<tr>
<td>Total</td>
<td>100 %</td>
</tr>
</tbody>
</table>

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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