Oryza

ORYZA OIL & FAT CHEMICAL CO., LTD.

GAMMA ORYZANOL

Food and Cosmetic Ingredient

■ **GAMMA ORYZANOL**
(For Food and Cosmetics)

■ **ORYZA GAMMA MILKY**
(Emulsion for Food and Cosmetics)

ORYZA OIL & FAT CHEMICAL CO., LTD.
Ver. 2.0HS

GAMMA ORYZANOL

1. Introduction

Rice has been widely cultivated as one of the major food resources and remains as staple food. With the advancement in refining technology, by-products of rice such as rice oil have been produced as edible vegetable oil as well as cosmetic ingredient. Rice play an important role as the only domestically produced resources of oil and fats.

Rice oil is loaded with bioactive compounds such as γ-oryzanol, tocopherols, tocotrienols, sterol *etc*., which contributed to the excellent stability and functionality of rice bran oil.

Since establishment of the industrial scale manufacturing of γ-oryzanol by Oryza Oil & Fat Chemical Co., Ltd., it has been widely used in food and cosmetic aspects around the world. It is registered as medicine in Japan and South Korea.

2. γ-oryzanol

γ-oryzanol is a naturally occurring component in rice bran and rice germ which consists of a mixture of ferulic acid esters of sterols and triterpene alcohols (Figure 1).

In 1954, Kaneko and Tsuchiya *et al.* [1-5] reported that isolated oryzanol demonstrated nutritional effects on animals. There are increasing numbers of reports indicating the benefits, efficacy and safety of γ-oryzanol.

Literature

1) Kaneko R., Tsuchiya T., *Proceedings of Industrial Research Institute of Tokyo*, **49**, 142 (1954).
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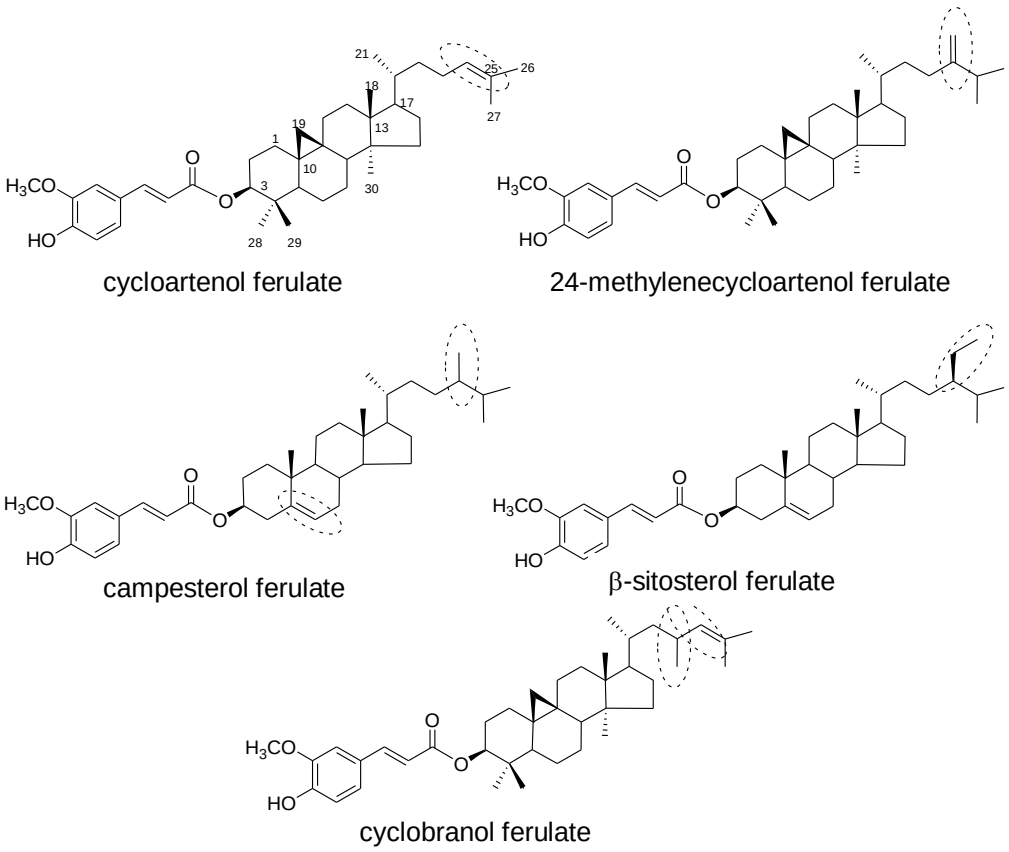


Figure 1 Chemical structures of major components of γ-oryzanol

3. Functional Effects of γ-oryzanol

3-1. Effect on Central Nervous System and Mental Condition

There are a number of clinical studies reported that γ-oryzanol is beneficial in the treatment of relieving menopausal (climacteric) symptoms (Table 1). Meanwhile, Sasaki *et al.* [5] reported that γ-oryzanol improved the condition of post traumatic dysautonomia from head injuries and no side effects reported at large dosage (Tables 2 and 3).

In addition, combination of γ-oryzanol and plant sterol has been used in the treatment of senile dementia, arteriosclerosis and cerebromalacia. The mechanism of action of γ-oryzanol is believed to be involved in the metabolism of catecholamine in the hypothalamus [6].

Other studies demonstrated the anti-ulcer effect of γ-oryzanol in rat with gastric mucosal damage in water immersion restraint stress model [7] and in mice gastric mucosal injury model with conditioned emotional stimuli [8], the anti-ulcer effect is believed to be involved in the metabolism of catecholamine.

Table 1: The effect of γ-oryzanol on menopausal symptoms and dysautonomia.

Application	Dosage (mg/d)	Duration (day)	Effect	Ref. literature
Menopause	5-10	10-38	>50% reduction of menopausal index	1
	90	14	76.6% improvement in symptoms	2
	15-30	7-14	70-90% improvement in dysautonomia	3
	300	4-8 weeks	80% elevation of symptoms & reduce serum lipid peroxide	4
Dysautonomia	135	21	74% effectiveness	5

Table 2: The effect of γ-oryzanol on the duration of illness of dysautonomia & post trauma from head injury.

Dysautonomia			
Duration of illness (years)	Number of cases	Effectiveness	Ineffectiveness
0-1	12	7 (22.6%)	5 (16.1%)
1-4	14	11 (35.5%)	3 (9.6%)
4-8	2	2 (6.5%)	0 (0%)
8-12	2	2 (6.5%)	0 (0%)
12-20	1	1 (3.2%)	0 (0%)
Total	31	23 (74.3)	8 (25.7%)
Post Trauma from Head Injury			
Duration of illness (year)	Number of cases	Effectiveness	Ineffectiveness
0-1	5	3 (27.3%)	2 (18.2%)
1-4	5	3 (36.3%)	1 (9.1%)
21	1	1 (9.1%)	0 (0%)
Total	11	8 (72.7%)	3 (27.3%)

Table 3: The effect of γ-oryzanol on gynaecological autonomic nervous system.

		No.	Very Effective (++)	Effective (+)	Mildly effective (+)	No changes (-)
1	Middle aged Neuropathy	17	3 (18.0)	8 (47.0%)	4 (23.5%)	2 (11.5%)
2	Menopausal Neuropathy	18	5 (27.7)	7 (38.9%)	4 (23.5%)	2 (11.1%)
3	Hysterectomy	5		4 (80.0%)	1 (20.0%)	
Total		40	8 (20.0)	19 (50.0%)	6 (20.0%)	4 (10.0%)

3-2. Antioxidant Effect

The antioxidant effect of γ-oryzanol was well documented and excellent in inhibiting lipid peroxidation. Kanno *et al* [9] reported that γ-oryzanol (0.5% ~1%) inhibited thermal oxidative polymerization of soybean oil. The antioxidant effect of γ-oryzanol is contributed by ferulic acid entity, meanwhile, BHT and δ-tocopherol has been revealed to be heat resistant. In addition, Oryza Oil & Fat Chemical Co. Ltd. showed that the antioxidant effect of γ-oryzanol was potentiated with amino acid [10]. According to Rodin's iron method, the induction period of certain peroxide was measured, as illustrated in Figure 2, there was synergistic increased in antioxidant effect of γ-oryzanol and amino acids.

The excellent heat resistance property of γ-oryzanol is highly suitable to be incorporated in heat processed food. Currently in Japan, γ-oryzanol is approved and listed as "antioxidant" under the list of chemical composition of food additives.

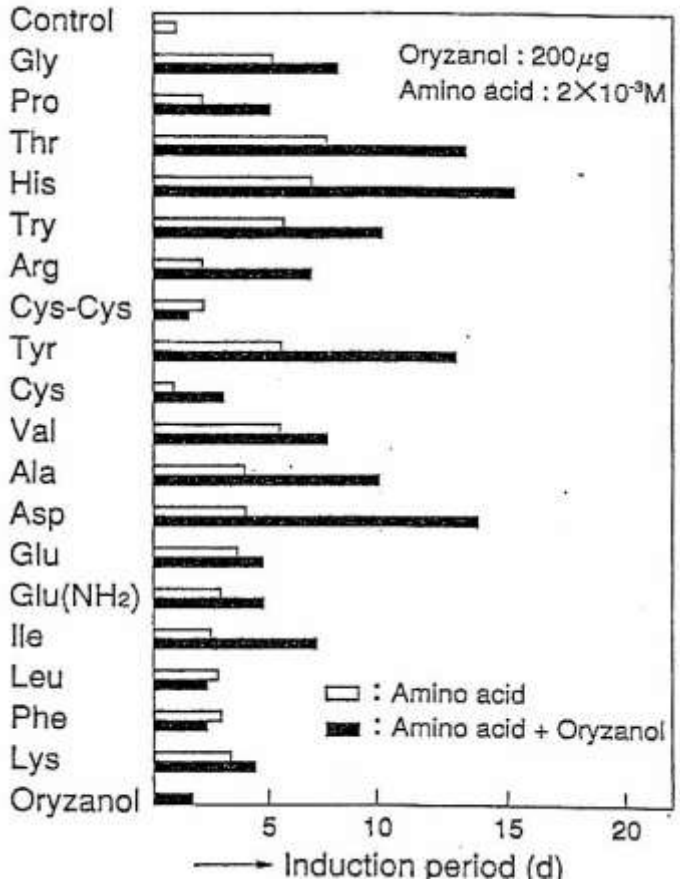


Figure 2: The Antioxidant Effect of γ-oryzanol and in combination with amino acids.

3-3. Topical Effect

(a) Increased skin temperature

Kamimura *et al.* [11-13] reported that topical application of γ-oryzanol increased skin surface temperature (Table 4). In the experiment, hydrophilic ointment of γ-oryzanol was applied to the back of sheared rabbit prior to cold exposure, changes on skin temperature was measured and recorded. In addition, intravenous administration of radioactive phosphorus compound increased skin surface glands (Table 5), γ-oryzanol acted as cold load preventing sudden fall of skin temperature while promoting the recovery of skin temperature. Besides, it was shown that oral administration (human) of γ-oryzanol improved circulation of the skin resulting in increased skin surface temperature.

Table 4: Average Skin Temperature after Cold Exposure of applied areas.

Area	21°C	5°C	0°C	-10°C
2% ointment (°C)	35.8	32.2	30.5	27.9
1% ointment (°C)	35.8	32.1	30.6	27.8
Contrast area (°C)	35.8	31.3	29.6	26.0

Table 5: Ratio of Topical application of γ-oryzanol to CPM

Rabbit	P_{32}	2% ointment	1% ointment	Contrast area
1	0.2mc	1.08	1.06	1.00
2	0.2mc	1.06	1.03	
3	0.1mc	1.04	1.04	
4	0.1mc	1.16	1.19	
5	0.1mc	1.10	1.09	
6	0.1mc	1.16	1.13	
Ratio		1.10	1.09	

(b) Skin Whitening & Activation of Sebaceous Gland

Ibata *et al.* [14] examined the effect of γ-oryzanol on tyrosinase and the effect was compared with L-ascorbic acid. Result showed that tyrosinase activity and melanin production was inhibited by γ-oryzanol with a weaker effect compared to L-ascorbic acid. Clinically, intradermal administration of γ-oryzanol 10 mg improved the condition of liver spots [15]. Originally, γ-oryzanol was reported to absorb UV ray [16], meanwhile Ando *et al.* [17] reported that topical application of γ-oryzanol reduced erythema in UV-induced guinea pig model.

On the other hand, study showed that γ-oryzanol was stimulatory on sebaceous gland [18]. Topical application of γ-oryzanol 1% ointment alleviated the symptoms of dryness in atopic dermatitis and dry skin [19]. As illustrated in Figure 3 in page 8, topical application of γ-oryzanol aqueous cream 3 times daily for 12 weeks on inflammatory dry skin conditions reduced sebaceous gland secretion while regulating the function of sebaceous gland over long period of time. Hence, γ-oryzanol was potentially beneficial for dry skin condition (Figure 3). Research conducted by Kakuma *et al.* [20] on the effect of topical application on regulation of sebaceous gland reported that slow-acting γ-oryzanol promoted film formation on sebaceous gland and thus preventing dry skin and skin irritations.

In addition, γ-oryzanol has been incorporated as antioxidant in cosmetic applications [21].

3-4. Alleviation of hyperlipidemia & hypercholesterolemia

Wilson T. A. *et al.* reported that γ-oryzanol reduced plasma cholesterol in hypercholesterolemic hamsters [22]. Similarly, Hiramatsu K. *et al.* reported that γ-oryzanol suppressed the accumulation of cholesterol in arterial endothelium (atheroma) in hypercholesterolemic rabbits [23]. Clinically, oral intake of rice bran oil (containing naturally occurring γ-oryzanol) and γ-oryzanol (prescribed medicine) [25-27] has been shown to alleviate hypercholesterolemia and hyperlipidemia (Table 6).

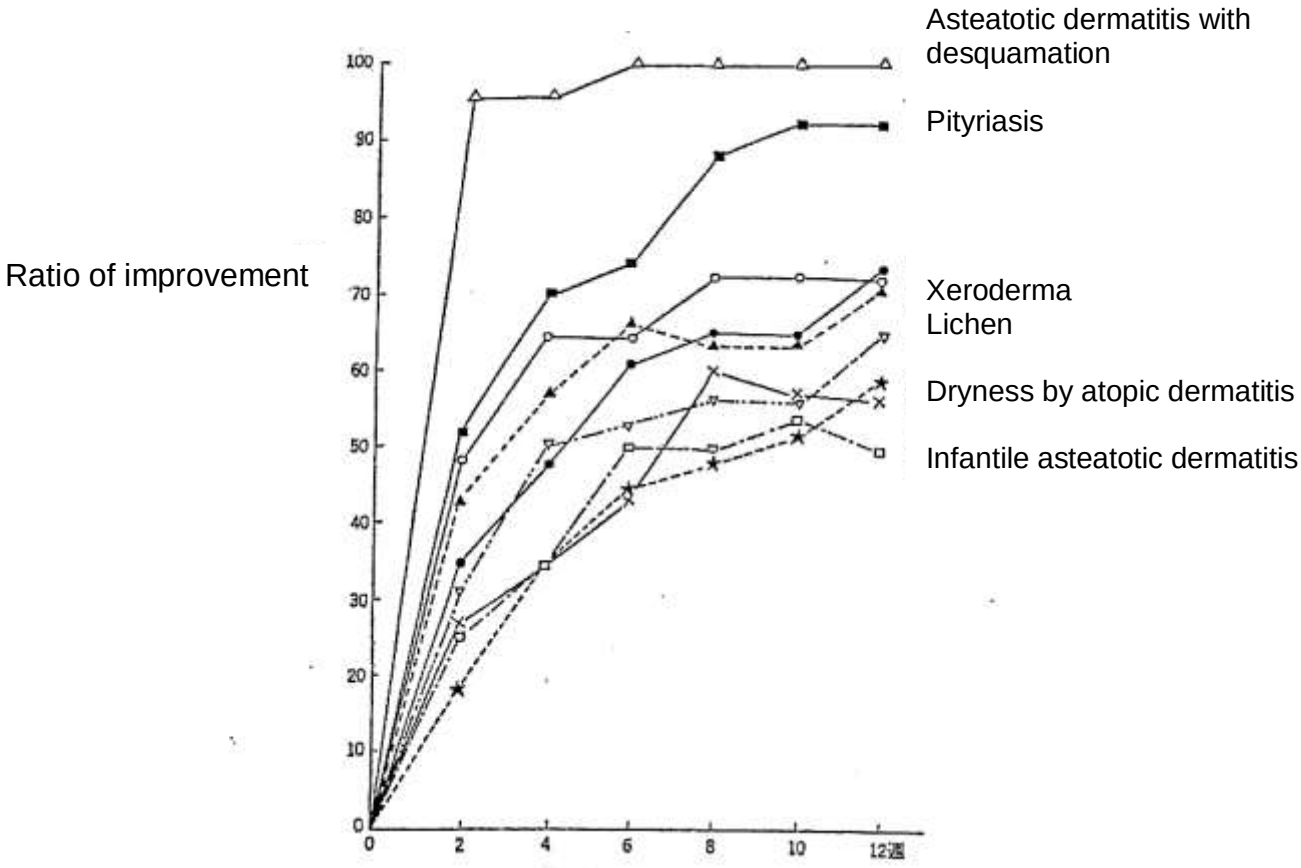


Figure 3 Improvement of various skin condition by topical application of γ-oryzanol

Table 6 The effect of γ-oryzanol (500 mg/day) on plasma cholesterol and triglycerides (Ref. literature no. 26)

Treatment Duration (week)	Initial concentration of cholesterol (mg/dL)		
	>260	220-260	<220
0	282±16	239±11	200±19
4	258±33	229±19*	198±23
8	259±24*	231±25	199±17
12	256±39	229±17*	196±32
16	251±24*	227±21*	191±32

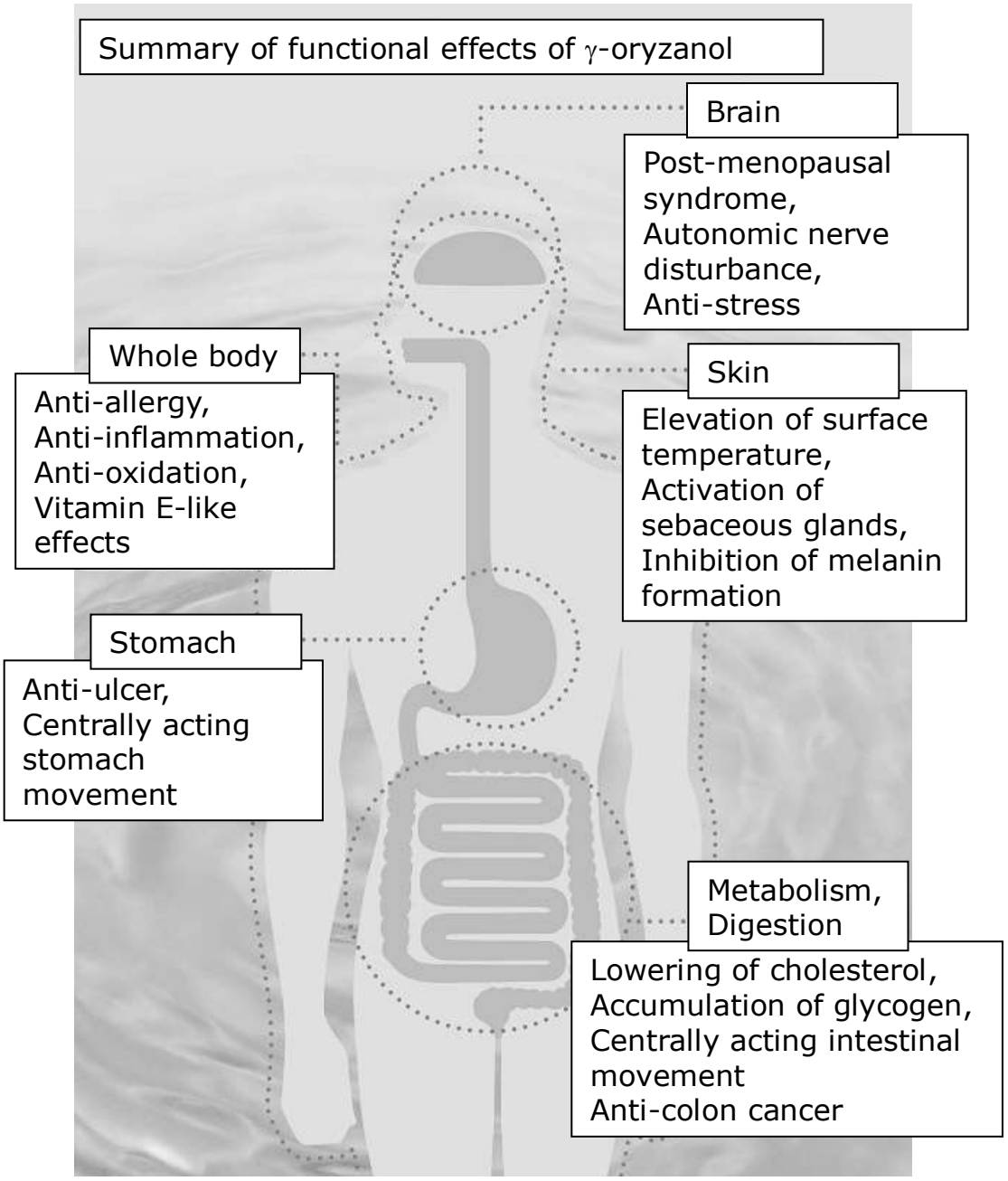
Mean±S.D., n=7-21

Treatment Duration (week)	Initial concentration of cholesterol (mg/dL)		
	>300	300-150	<150
0	396±97	197±44	106±24
4	308±30	214±80	123±42
8	291±64*	203±80	122±72
12	262±82*	210±99	131±34*
16	281±75*	197±75	123±68

Mean±S.D., n=4-20

3-5. Others

γ-oryzanol has been advocated as treatment for relieving menopausal symptoms [28]. Besides, Oka T. *et al.* reported that cycloartenyl ferulate, a component of rice bran oil-derived γ-oryzanol inhibit mass cells degranulation [29]. Islam M.S. *et al.* indicated the anti-inflammatory effects of γ-oryzanol in colitis induced by dextran sulphate sodium in ulcerative colitis in mice, NF κB has been shown to be involved in the mechanism of action [30].



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4. γ-oryzanol – absorption, distribution and metabolism

Fujiwara *et al.* [1] reported that plasma concentration of metabolite of γ-oryzanol peaked at 4 to 5 hours post administration, and decreasing rapidly to certain level and remained for 48 hours in rabbit. Meanwhile, 5-10% of metabolites found in the urinary excretion and 17-32% in the feces respectively after 48-hour administration [2]. In terms of distribution, γ-oryzanol was found to be largely distributed in the brain with its metabolite uniformly distributed among organs and largely accumulated in the liver however less in the reproductive organs.

Later, study conducted by Noda *et al.* [4, 5] using rats model reported that plasma concentration of γ-oryzanol peaked at 5 hours after oral administration and 10 hours by subcutaneous administration. However, single dose administration did not reveal a large distribution in the brain, continuous administration may result in 5-10 folds of distribution.

Literature

1) Fujiwara H. *et al.*, *Yakubutsu Ryoho*, **5** (11), 123-30 (1972).
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5. Nutritional Profile

Description	Value	Range	Remark	Analytical Method
Water	0.2g/100g			Heat-drying at atmospheric pressure
Protein	<0.1g		1	Kjeldahl method
Fat	99.8g/100g			Ethanol extraction method
Ash	0g/100g			Direct Incineration
Sugar	0g/100g		2	
Energy	898kcal/100g		3	
Fiber	Not detected	0.5g/100g	4	Enzymatic
Sodium	Not detected	0.1mg/100g		Atomic absorption spectrophotometry

Remarks:
1. Nitrogen-Protein conversion factor 6.25
2. Labelling Standard of Nutrition (Ministry of Health and Welfare Notification No. 146, 1996) according to conversion formula :
   100 - (moisture + protein + lipid + ash + dietary fiber)
3. Standard of Energy Expression (Ministry of Health and Welfare Notification No. 146, 1996) according to the conversion factor:
   Protein 4, Fat 9, Sugar 4
4. AOAC method.

Test Trustee: Japan Food Analysis Centre
Date of Test: Dec 14, 1998
Test Report: No. 398110460-001

6. Safety Profile

6-1. Acute Toxicity

Yahara *et al.* [1)] in a study using mouse and rats model reported that oral and intraperitoneal administration of γ-oryzanol 10,000 mg/kg showed no abnormality generally and upon autopsy. Similarly, no abnormalities observed on subcutaneous administration of γ-oryzanol 500 mg/kg.

6-2. Chronic Toxicity

It has been reported that no abnormal finding observed in rats after 6 months continuous oral administration of γ-oryzanol (30-1000 mg/kg) [2)].

6-3. Teratogenicty

No fetal teratogenicity observed in mouse with the administration of γ-oryzanol (6 – 600 mg/kg) during pregnancy. [3)]

6-4. Carcinogenicity

Oral administration of γ-oryzanol (2000 mg/kg) was given to mouse for 72 weeks and rat for 2 years respectively. No carcinogenicity observed at the above dosage. [4, 5)]

6-5. Skin Irritation Test (Patch Test)

Kobayashi T *et al.* reported that low skin irritation observed in skin patch test using γ-oryzanol 1% ointment. [6)]

Literature:

1) Yahara M. *et al.*, *Kiso to Rinsho*, **7**, 2781-85 (1973)
2) Hasato H. *et al.*, *Kiho to Rinsho*, **8**, 3417-35 (1974).
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7. Applications

Category	Examples
Food	Soft capsules, tablets, hard capsules, *etc*.
Cosmetics	Soap, facial wash, shampoo, conditioner, lotion, lotion, foundation, lip balm, lipstick, toothpaste, *etc.*

8. Packing

GAMMA ORYZANOL (Food Additives and Cosmetics): 5kg
Interior packing: plastic bag, cans
Exterior packing: carton

ORYZA GAMMA MILKY (Food and Cosmetics): 5kg
Interior packing: cans
Exterior packing: carton

9. Storage

Store under room temperature in dark place in sealed condition. Avoid places with high temperature and high humidity.

10. Expression

Food

GAMMA ORYZANOL: γ-oryzanol, oryzanol

ORYZA GAMMA MILKY: Vegetable oil, glycerin, glycerin fatty acid ester, γ-oryzanol, lecithin

Note: *Please follow the regulations of the countries of sales. In some countries, the usage of gamma-oryzanol is restricted as food additive or medicine.*

Cosmetic (INCI Name)

GAMMA ORYZANOL: ORYZANOL

ORYZA GAMMA MILKY: GLYCERIN, WATER, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYGLYCERYL-10 OLEATE, ORYZANOL, LECITHIN

PRODUCT STANDARD

PRODUCT NAME

GAMMA ORYZANOL

(FOOD & COSMETIC)

〈**STANDARD AND EXAMINATION METHOD**〉

This product is extracted and refined from the rice bran of *Oryza sativa* Linne (Gramineae). Dried product contains minimum of 98.0 % γ-oryzanol ($C_{40}H_{58}O_4$).

1.Appearance White or light yellowish crystalline powder. Inert Smell.

2.Certification Test

(1) The maximum absorbance wavelength of this product in n-heptane solution (1→ 100,000) is at 231nm, 291nm and 315nm.

(2) To 0.01 g of this product, add 10 ml of Potassium hydroxide-ethanol. After heating, a yellow color develops.

(3) Dissolve 0.01 g of this product with 2 ml of acetone, add 0.1 ml of ferric chloride/ethanol solution (1→50). A green to yellow-green color develops.

3.Content of γ-Oryzanol Min. 98.0 %

(QUANTITATIVE ANALYSIS)
Dry this product at 105°C for 1 hour , collect 0.01g of this product follow by addition of 80ml of n-heptane to 100ml, dissolve the mixture at room temperature with supersonic wave. Collect 10ml of the solution follow by addition of n-heptane to 100ml. At length layer of 10mm, absorbance is measured at wavelength 315nm.

$$\text{Quantity of γ- oryzanol (\%)} = \frac{E \times 100}{W \times 359}$$

E: Absorbance
W: γ- oryzanol weight (g) in 100 ml of sample solution used for measurement.
359: extinction coefficient of γ- oryzanol E (1%, 1cm)

4.Loss on Drying	Max. 0.5 %	(Analysis for Hygienic Chemists, 1g, 105°C, 1h)
5.Ignition Residue	Max. 0.5 %	(The Japanese Standards for Food Additives)

6.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)
7.Standard Plate Counts	Max. $1x10^2$ cfu/g	(Analysis for Hygienic Chemists)
8.Moulds and Yeasts	Max. $1x10^2$ cfu/g	(Analysis for Hygienic Chemists)
9.Coliforms	Negative	(Analysis for Hygienic Chemists)

10.Composition

Ingredient	Content
γ-oryzanol	100%

Note: *Please follow the regulations of the countries of sales. In some countries, the usage of gamma-oryzanol is restricted as food additive or medicine.*

PRODUCT STANDARD

PRODUCT NAME

ORYZA GAMMA MILKY

(FOOD)

This product is white milky emulsion which contains a minimum of 5% γ-oryzanol ($C_{40}H_{58}O_4$:602.90) emulsified with high quality of emulsifying agents.

1.**Appearance** Viscous white or light yellowish emulsion with unique smell.

2.**Identification** When 2g of this product is dissolved and heated with potassium hydroxide ethanolic solution, there occurs yellow coloring. (γ-oryzanol)

3.**Content of γ-Oryzanol** Min. 5.0 %

(QUANTITATIVE ANALYSIS)
Dissolving 0.03 g of this product to ethanolic solution until it becomes 100 ml. If this solvent is cloudy, filtrate with filter paper. Putting this solvent into a quartz cell which layer length is 10 mm, measuring its absorbance on 325 nm wavelength. Calculate the contents of γ- oryzanol using the following formula with the measured absorbance (E).

$$\text{Quantity of γ- oryzanol (\%)} = \frac{E \times 100}{W \times 359}$$

E: Absorbance
W: γ- oryzanol weight (g) in 100 ml of sample solution used for measurement.
359: extinction coefficient of γ- oryzanol E (1%, 1cm)

4.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)
5.Standard Plate Counts	Max. $1x10^3$ cfu/g	(Analysis for Hygienic Chemists)
6.Moulds and Yeasts	Max. $1x10^2$ cfu/g	(Analysis for Hygienic Chemists)
7.Coliforms	Negative	(Analysis for Hygienic Chemists)

8.Composition

Ingredients	Contents
Glycerin	40%
Purified water	25%
Caprylic/capric acid triglyceride	15%
Glycerin ester of fatty acid	12%
γ-oryzanol	5%
Lecithin	3%
Total	100%

Note: *Please follow the regulations of the countries of sales. In some countries, the usage of gamma-oryzanol is restricted as food additive or medicine.*

PRODUCT STANDARD

PRODUCT NAME

ORYZA GAMMA MILKY

(COSMETIC)

This product is milky white liquid which contains a minimum of 4.0 – 6.0 % γ- oryzanol ($C_{40}H_{58}O_4$) emulsified with high quality of emulsifying agents.

1.**Appearance** Viscous white or light yellowish emulsion with unique smell

2.**Identification**

(1) γ- oryzanol
The absorbance at the maximum wave length of ethanolic solution (1→5000) is at 325 nm.

(2) Triglyceride
When analysis is performed by gas chromatography (Column temperature: 120°C), peaks of standard solution (caprylic acid, capric acid) and sample solution show same retention time.

(3) Glycerin ester of fatty acid
When analysis is performed by gas chromatography (Column temperature: 200°C), peaks of standard solution (oleic acid) and sample solution show same retention time.

(4) Glycerin
10 g of this product is dissolved in 50 ml 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.

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

3.**Content of γ -Oryzanol** Min. 4.0 – 6.0%

(QUANTITATIVE ANALYSIS)
Dissolve 0.03 g of this product to ethanolic solution until it becomes 100 ml. If this solvent is cloudy, filtrate with filter paper. Putting this solvent into a quartz cell which layer length is 10 mm, measuring its absorbance on 325nm wavelength. Calculate the contents of γ- oryzanol using the follo wing formula with the measured absorbance (E).

$$\text{Quantity of γ- oryzanol (\%)} = \frac{E \times 100}{W \times 359}$$

E: Absorbance
W: γ- oryzanol weight (g) in 100 ml of sample solution used for measurement.
359: extinction coefficient of γ- oryzanol E (1%, 1cm)

4.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)
5.Standard Plate Counts	Max. $1x10^2$ cfu/g	(Analysis for Hygienic Chemists)
6.Moulds and Yeasts	Negative	(Analysis for Hygienic Chemists)
7.Coliforms	Negative	(Analysis for Hygienic Chemists)

8.Composition

Ingredients	Contents
GLYCEROL	40%
WATER	25%
CAPRYLIC/CAPRIC TRIGLYCERIDE	15%
POLYGLYCERYL-10 OLEATE	12%
ORYZANOL	5%
LECITHIN	3%
Total	100%

Ref. The Japanese Standard of Quasi-Drug 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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