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. 3.3 YF

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.

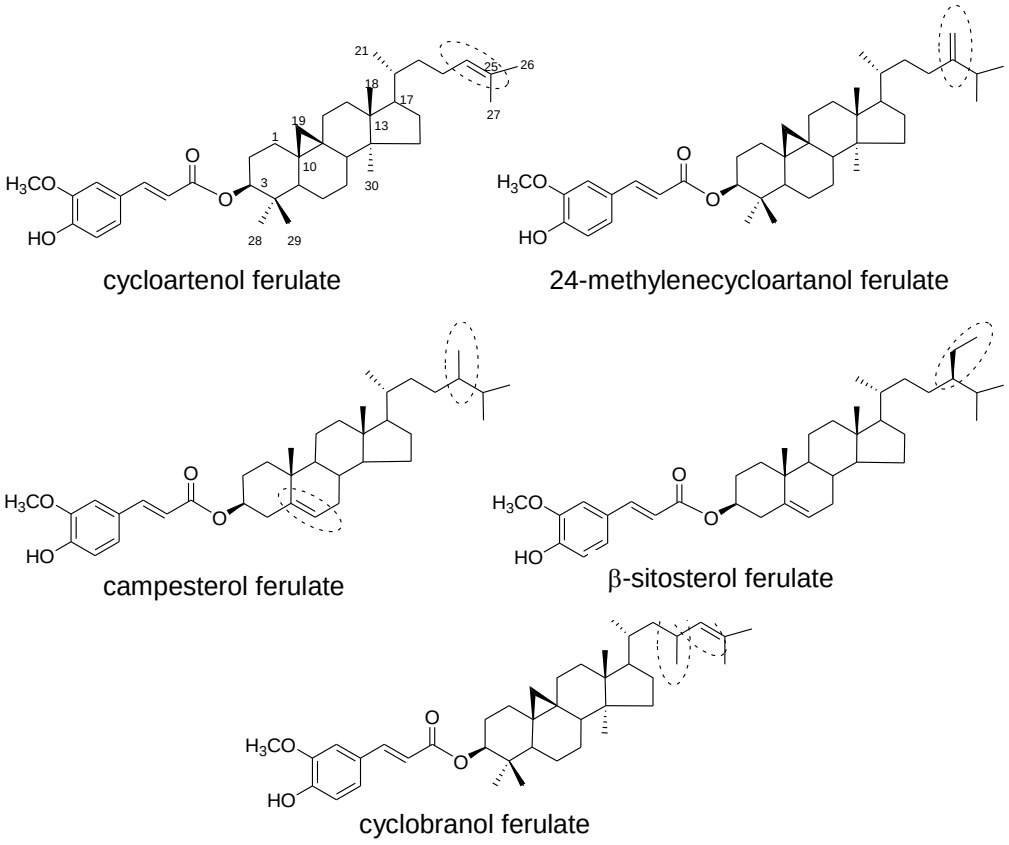


Figure 1 Chemical structures of major components of γ-oryzanol

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) [6-10]. Meanwhile, Sasaki *et al.* [10] 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 [11].

Other studies demonstrated the anti-ulcer effect of γ-oryzanol in rat with gastric mucosal damage in water immersion restraint stress model [12] and in mice gastric mucosal injury model with conditioned emotional stimuli [13], 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	6
	90	14	76.6% improvement in symptoms	7
	15-30	7-14	70-90% improvement in dysautonomia	8
	300	4-8 weeks	80% elevation of symptoms & reduce serum lipid peroxide	9
Dysautonomia	135	21	74% effectiveness	10

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* [14] 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 [15]. 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.

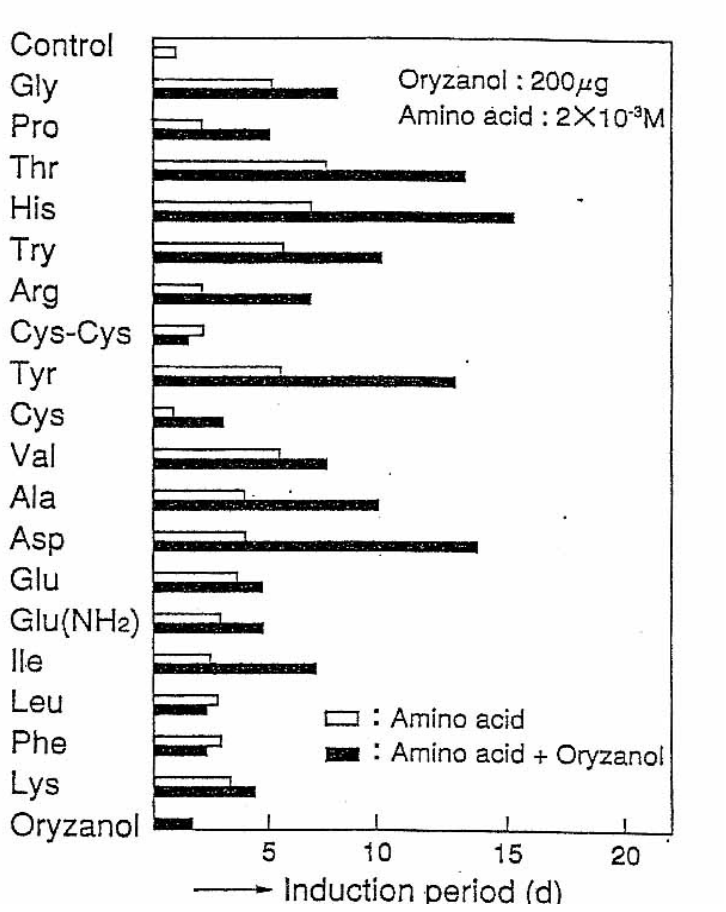


Figure 2: The Antioxidant Effect of γ-oryzanol and in combination with amino acids.

3-3. Alleviation of hyperlipidemia & hypercholesterolemia

Wilson T. A. *et al.* reported that γ-oryzanol reduced plasma cholesterol in hypercholesterolemic hamsters [16]. Similarly, Hiramatsu K. *et al.* reported that γ-oryzanol suppressed the accumulation of cholesterol in arterial endothelium (atheroma) in hypercholesterolemic rabbits [17].Clinically, oral intake of rice bran oil [18] (containing naturally occurring γ-oryzanol) and γ-oryzanol (prescribed medicine) [19-21] has been shown to alleviate hypercholesterolemia and hyperlipidemia (Table 4).

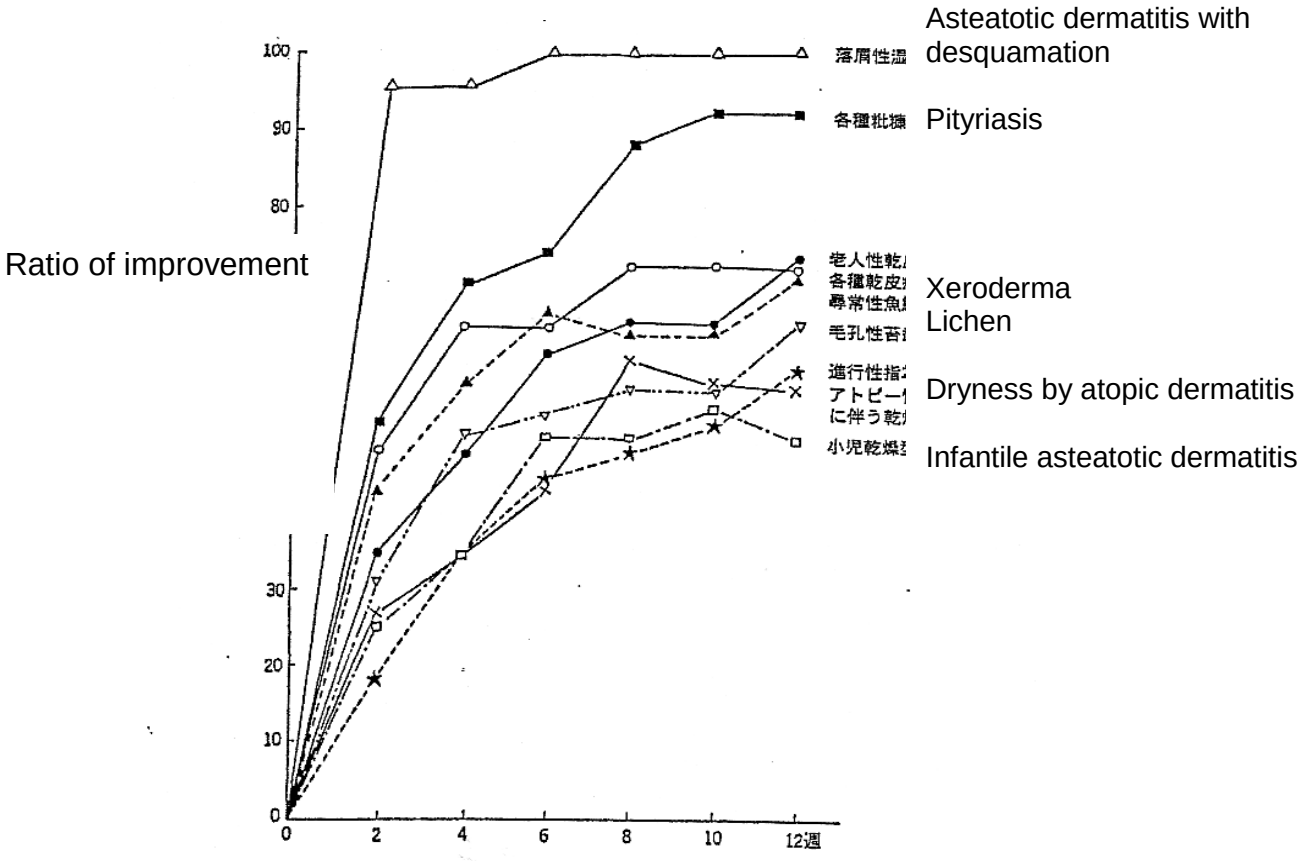


Figure 3 Improvement of various skin condition by topical application of γ-oryzanol

Table 4 The effect of γ-oryzanol (500 mg/day) on plasma cholesterol and triglycerides
(Ref. literature no. 21)

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

3-4. Anti-inflammatory effect

It has been reported that cycloartenyl ferulate, a major component of γ-oryzanol, inhibits activation of NFκB by LPS dose-dependently [22]. Furthermore, γ-oryzanol and cycloartenyl ferulate is also reported to strongly inhibit genes expression such as TNFα, IL-1β, COX-2, iNOS which are involved in inflammation. These results suggest that γ-oryzanol is found to be useful for inflammatory disease.

Inflammatory bowel diseases such as ulcerative colitis and Crohn's disease have been designated as intractable diseases by the Health, Labour and Welfare Ministry of Japan. Oral administration to dextran sulphate sodium in mice is known to provoke bowel inflammation closely resembling ulcerative colitis. Oral administration or injection of γ-oryzanol is reported to alleviate inflammation dramatically and it is revealed that the inhibitory effect of NFκB activation is involved in this result [23].

These results suggest that γ-oryzanol is useful for relief of symptoms of inflammatory bowel diseases.

3-5. Antiallergenic effect

Allergenic reaction occurs in processes as follows: 1) antigen-specific IgE binds to FcεR1 receptor on mast cells, 2) intracellular calcium concentration rises, 3) degranulatory response is raised, and histamine and prostaglandin D2 are released.

γ-Oryzanol is reported to inhibit dose-dependently degranulatory response by stimulated by antigen in rat-derived mast cells. It is reported that this effect of γ-oryzanol is stronger than tranilast, a kind of antiallergenic agent offered commercially, and no effect of ferulic acid is observed. Mechanism of this effect is considered that γ-oryzanol captures IgE, prevents it from binding to FcεR1, and attenuates mast cell degradation. [24].

Furthermore, γ-oryzanol is known to inhibit prominently passive cutaneous anaphylaxis reaction caused by IgE topical administration.

3-6. Topical Effect
(a) Increased skin temperature

Kamimura *et al.* [25-27] reported that topical application of γ-oryzanol increased skin surface temperature (Table 5). 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 6), 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 5: 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 6: 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

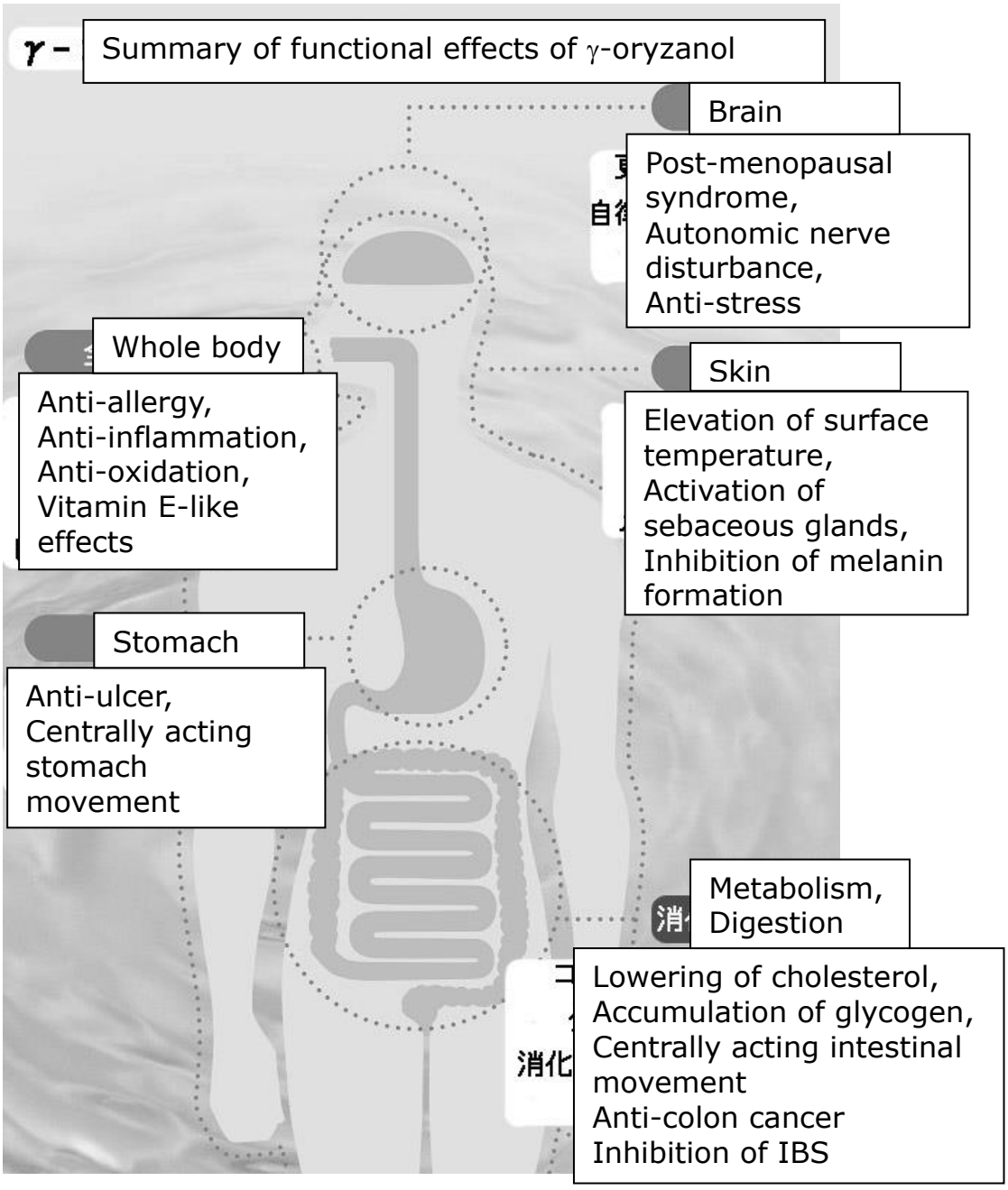
Ibata *et al.* [28] examined the effect of γ-oryzanol on tyrosinase and the effect was compared with L-ascorbic acid. Result showed that tyrosinase activity and melanin production was inhibited by γ-oryzanol with a weaker effect compared to L-ascorbic acid. Clinically, intradermal administration of γ-oryzanol 10 mg improved the condition of liver spots [29]. Originally, γ-oryzanol was reported to absorb UV ray [30], meanwhile Ando *et al.* [31] 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 [32]. Topical application of γ-oryzanol 1% ointment alleviated the symptoms of dryness in atopic dermatitis and dry skin [33]. 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.* [34] 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 [35].

3-7. Others

γ-oryzanol has been advocated as treatment for relieving menopausal symptoms [36].


γ－
Summary of functional effects of γ-oryzanol
Brain
Post-menopausal syndrome, Autonomic nerve disturbance, Anti-stress
Whole body
Anti-allergy, Anti-inflammation, Anti-oxidation, Vitamin E-like effects
Skin
Elevation of surface temperature, Activation of sebaceous glands, Inhibition of melanin formation
Stomach
Anti-ulcer, Centrally acting stomach movement
Metabolism, Digestion
Lowering of cholesterol, Accumulation of glycogen, Centrally acting intestinal movement
Anti-colon cancer
Inhibition of IBS

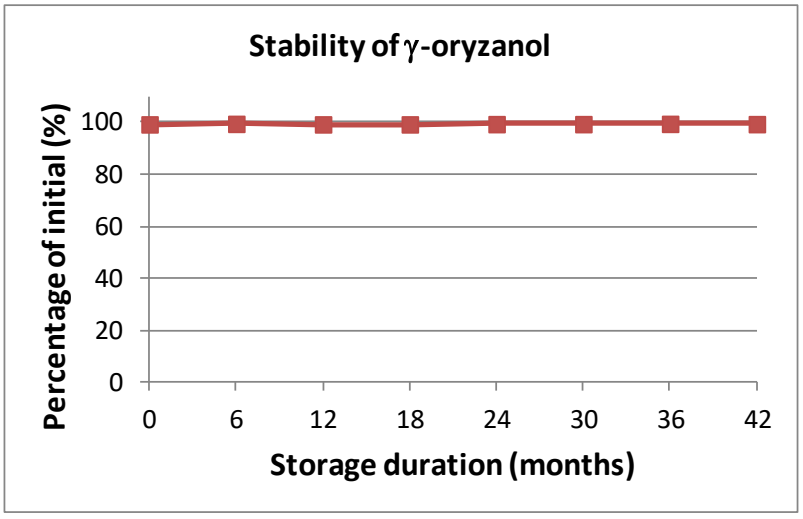
4. γ-oryzanol – absorption, distribution and metabolism

Fujiwara *et al.* [37] 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 [38]. 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 [39].

Later, study conducted by Noda *et al.* [40, 41] 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.

5. Stability

γ-oryzanol content was not decreased at proper storage conditions up to 42 months.



6. 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

7. Safety Profile

7-1. Acute Toxicity

Yahara *et al.* [42] 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.

7-2. 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) [43].

7-3. Teratogenicty

No fetal teratogenicity observed in mouse with the administration of γ-oryzanol (6 – 600 mg/kg) during pregnancy. [44]

7-4. 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. [45, 46]

7-5. Skin Irritation Test (Patch Test)

Kobayashi T *et al.* reported that low skin irritation observed in skin patch test using γ-oryzanol 1% ointment. [47]

8. Applications

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

9. 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

10. Storage

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

11. 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

12. Recommended dosage

Claim	Recommended dosage	Reference
Postmenopausal syndrome (PMS)	5 ~ 300 mg / day	6-9
Dysautonomia	130 ~ 140 mg / day	10
Improvement of hyperlipidemia & hypercholesterolaemia	50 ~ 800 mg / day	48

13. Literature

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PRODUCT STANDARD

PRODUCT NAME

GAMMA ORYZANOL

(FOOD)

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

Appearance	White or slightly yellow colored crystal or crystalline powder. It has no smell or slightly unique smell.	
Certification Test	(1) The absorbance at the maximum wave length of n-Heptane solution (1→100,000) is at 231 nm, 291 nm, and 315 nm. (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). Green to yellow-green color develops.	
Content of γ-Oryzanol	Min. 98.0 %	(UV)
Loss on Drying	Max. 0.5 %	(Analysis for HygienicChemists, 1g, 105 ℃, 1 hr)
Ignition Resdue	Max. 0.5 %	(The Japanese Standards for Food Additives)
Purity Test		
(1)Heavy Metals (as Pb)	Max. 10 ppm	(Sodium Sulfide Colorimetric Method)
(2)Arsenic (as As_2O_3)	Max. 1 ppm	(Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B)
Standard Plate Counts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Moulds and Yeasts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Coliforms	Negative	(Analysis for Hygienic Chemists)

Composition

Ingredient	Content
γ-oryzanol	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.

PRODUCT STANDARD

PRODUCT NAME

ORYZA GAMMA MILKY

(FOOD)

This product is milky white liquid which contains more than 5% of γ-oryzanol ($C_{40}H_{58}O_4$) emulsified with high quality of emulsifying agents.

Appearance	This product is white or slightly yellow colored sticky liquid. It has unique smell.	
Identification (γ -oryzanol)	When 2g of this product is dissolved and heated with potassium hydroxide ethanolic solution, there occurs yellow coloring.	
γ -Oryzanol	Min. 5.0 %	(UV spectrophotometry)
Purity Test		
(1)Heavy Metals (as Pb)	Max. 10 ppm	(Sodium Sulfide Colorimetric Method)
(2) Arsenic (as As_2O_3)	Max. 1 ppm	(Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B)
Standard Plate Counts	Max. 1×10^3 cfu/g	(Analysis for Hygienic Chemists)
Moulds and Yeasts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Coliforms	Negative	(Analysis for Hygienic Chemists)

Composition

Ingredient	Content
γ -oryzanol	5 %
Glycerin	40 %
Caprylic/capric acid triglyceride	15 %
Glycerin ester of fatty acid	12 %
Lecithin	3 %
Purified water	25 %
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.

PRODUCT STANDARD

PRODUCT NAME

GAMMA ORYZANOL

(COSMETIC)

This product is extracted and refined from the rice bran of *Oryza sativa* Linne (Gramineae).

Dried product contains minimum of 98.0% γ-oryzanol ($C_{40}H_{58}O_4$).

Appearance	White or slightly yellow colored crystal or crystalline powder. It has no smell or slightly unique smell.	
Certification Test	(1) The absorbance at the maximum wave length of n-Heptane solution (1→100,000) is at 231 nm, 291 nm, and 315 nm. (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 Aceton, add 0.1 ml of Ferric chloride/ethanol solution(1→50). A green to yellow-green color develops.	
Content of γ-Oryzanol	Min. 98.0 %	(UV)
Loss on Drying	Max. 0.5 %	(Analysis for HygienicChemists, 1g, 105 ℃, 1 hr)
Ignition Resdue	Max. 0.5 %	(The First Method of The Japanese Standards of Quasi-Drug Ingredients, 1g)
Purity Test		
(1)Heavy Metals (as Pb)	Max. 10 ppm	(The Second Method of The Japanese Standards of Quasi-Drug Ingredients)
(2)Arsenic (as As_2O_3)	Max. 1 ppm	(The Third Method of The Japanese Standards of Quasi-Drug Ingredients)
Standard Plate Counts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Moulds and Yeasts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Coliforms	Negative	(Analysis for Hygienic Chemists)

Composition	Ingredient	Content
	γ-oryzanol	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.

PRODUCT STANDARD

PRODUCT NAME

ORYZA GAMMA MILKY

(COSMETIC)

This product is milky white liquid which contains more than 5% of γ -oryzanol ($C_{40}H_{58}O_4$) emulsified with high quality of emulsifying agents.

Appearance	This product is white or slightly yellow colored sticky liquid. It has unique smell.	
Identification (γ -oryzanol)	When 2g of this product is dissolved and heated with potassium hydroxide ethanolic solution, there occurs yellow coloring.	
γ -Oryzanol	Min. 5.0 %	(UV spectrophotometry)
Purity Test		
(1)Heavy Metals (as Pb)	Max. 10 ppm	(Sodium Sulfide Colorimetric Method)
(2) Arsenic (as As_2O_3)	Max. 1 ppm	(Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B)
Standard Plate Counts	Max. 1×10^3 cfu/g	(Analysis for Hygienic Chemists)
Moulds and Yeasts	Max. 1×10^2 cfu/g	(Analysis for Hygienic Chemists)
Coliforms	Negative	(Analysis for Hygienic Chemists)

Composition

Ingredient	Content
γ -oryzanol	5 %
Glycerin	40 %
Caprylic/capric acid triglyceride	15 %
Glycerin ester of fatty acid	12 %
Lecithin	3 %
Purified water	25 %
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.

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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ORYZA OIL & FAT CHEMICAL CO., LTD.