

NUTRAISO®

TECHNICAL BRIEF

 **Quintessence**™

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What is Nutralso®?

- Patented all-natural nutraceutical ingredient extracted from California rice insoluble bran fractions.
- Non-GMO, hypoallergenic and gluten-free.
- Rich in hydrolyzed highly digestible proteins, carbohydrates, antioxidants, and a broad range of micronutrients.
- Significantly more bioavailable nutrients in the human digestive tract than commercial rice bran due to patented hydrolyzation process for extraction.
- Scientifically documented to mitigate specific chronic health conditions including insulin resistance (prediabetic health), chronic malnutrition in lactating mothers and infants, and many health problems caused by nutrition deficits in seniors.
- Unique nutritional product for use as a dietary supplement and highly nutritious base ingredient in food products.



Unique Patented Extraction Process

- The bran of rice is an extremely nutrient dense by-product of rice milling, but...
 - It has typically not been used as human food because it is not readily digested in the human digestive tract and therefore the nutrients are not readily bioavailable.
 - Standard commercial rice bran extracts available on the market today are produced from a single enzyme extraction that leaves much of the nutritional value in the rice bran unavailable for human nutrition.
- Nutralso® is produced via a patented process using 7 different natural enzymes and strategically timed temperature treatments, resulting in release of the maximum available nutritional value from the bran.
- The Nutralso® enhanced hydrolyzation and extraction process is protected under US Patent No. 8,945,642 B2 which describes the unique extraction method used to obtain a “Nutritionally Enhanced Isolate of Stabilized Rice Bran”.

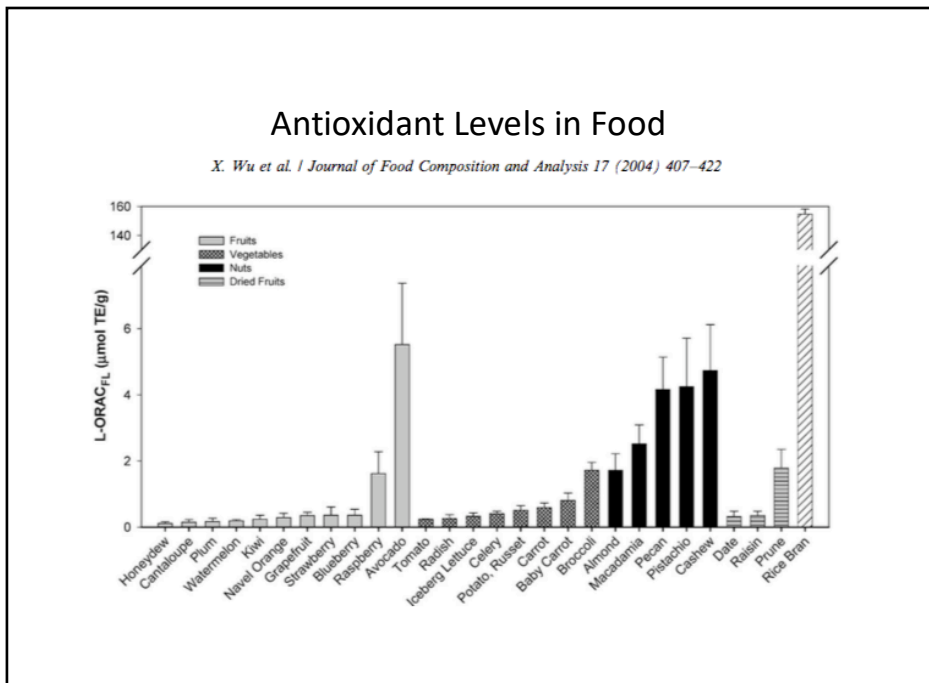


Why Stabilized Rice Bran?

- Stabilized Rice Bran (SRB) is the highest of all cereal grains in scientifically documented nutraceutical and pharmacological isolates for mitigating specific chronic health conditions.
- SRB is nutritionally rich in proteins, antioxidants, vitamins and minerals.
- However, SRB in its natural state is not beneficial in human food consumption because it is not easily digested in the human digestive tract, and consequently the valuable nutrients not readily bioavailable for human nutritional health and wellness. Nutralso® solves this problem.
- The Nutralso® patented stabilization and enhanced extraction process unlocks the nutritional potency of rice bran making it bioavailable for human digestion and nutritional wellness.
- Nutralso® enhanced bran extraction process (U.S. Patent No. 8,945,642 B2) accomplishes this bioavailability through a significantly enhanced hydrolyzation and multi-phase enzyme nutrient extraction regime rendering it an entirely new and FDA-DSHEA compliant nutritional supplement.

Antioxidants

- Oxidative stress occurs when the generation of free radicals and active intermediates in a system exceeds the body's ability to neutralize and eliminate them.
- Oxidative stress is implicated in numerous chronic health problems from cardiovascular to diabetes-related health conditions, like cholesterol, triglyceride and blood sugar imbalances.
- Antioxidants help combat oxidative stress.
- Rice bran is naturally high in antioxidants.
- The Nutralso® patented extraction process releases more hydrolyzed fats thereby increasing the bioavailability of antioxidants.
- Nutralso® ranks among the highest foods in antioxidant capacity, a key factor in achieving U.S. Patent 9,192,180 B2 for reducing insulin resistance.



Hydrolyzation is the Key

- Hydrolyzation involves using specific enzymes to cleave a substance into smaller component parts. The Nutralso® extraction method is optimized to maximize hydrolyzation of proteins, fats and carbohydrates to achieve the highest levels of nutrient bioavailability.
- **Complex proteins** – break into smaller, more digestible and absorbable pieces called peptides and free amino acids.
- **Fats** – break down into free fatty acids and antioxidant-rich fats that might otherwise be trapped in fiber and excreted.
- **Carbohydrates** – starches and cellulose break into less complex polysaccharides and simple sugars for greater absorption in the gastrointestinal tract.

Standard Enzyme Treatment (SET) vs QN Enhanced Enzyme Treatment (EET)				
	% Solids	Dry Basis Wt.	Fat	Protein
SET Extraction	7.14	7.45	0.93	0.83
EET Extraction	11.41	12.89	2.50	2.65
% Increase	59.8%	73.1%	167.6%	220.9%

- The more enhanced the enzyme hydrolyzation, the more bioavailable the proteins, fats, and carbohydrates are for absorption in the human digestive system.

What is Bioavailability?

- Bioavailability relates to the capacity of a nutrient to be absorbed into the gastrointestinal system and bloodstream, thus making the nutrient more bioactive (efficacious) in the human body for the health and wellbeing of the recipient.
- Nutralso® uses a patented extraction process using seven different enzymes and strategically timed temperature treatments to modify the fats and proteins in rice bran, breaking them into less complex forms that can be more readily absorbed in the human digestive system.
- Nutralso’s process “pre-digests” rice bran so the human body can absorb and utilize the maximum amount of its bioavailable nutrients.
- Standard industry 100 gram analyses only measure aggregated total amounts of nutrients, not the hydrolyzed nutritional bioavailability achieved by the Nutralso® proprietary extraction process.
- In review of the Nutralso® patent by the USPTO, the examiner concluded that; ***“[Nutralso] is a novel rice bran isolate wherein the bulk properties of the protein mixture is “significantly more” than that of the native protein in rice bran... The nutritionally enhanced isolate of [Nutralso] is a mixture of hydrolyzed protein, hydrolyzed starch and high quality rice bran oil.”***

Nutralso® Clinical Results – Infant Nutrition

- A clinical trial conducted in Guatemala in 2014 evaluated the impact of Nutralso® Enhanced Rice Bran Extract in the diet of 129 lactating mothers on their breastfed infants.
- By adding Nutralso® to the mothers’ diets:
 - Infants showed improvement in all five World Health Organization (WHO) growth factors.
 - Mothers reported increased milk production.

Results in WHO Infant Growth Indicators							
Anthropometric indicator	Initial Z ² Score (1.5-months old)			Final Z Score (6-months old)			p-value ¹
	n	Mean ± st.dev.	Percentile	n	Mean ± st.dev .	Percentile	
Weight-for-Height (WFA)	153	+1.17 ± 1.3	56.75	129	+0.53 ± 1.0	70.19	0.0089
Length-for-Age (LFA)	153	-1.90 ± 1.21	2.87	129	-1.78 ± 1.0	3.75	0.3473
Weight-for-Age (WFA)	153	-1.60 ± 1.3	5.48	129	-0.79 ± 1.0	21.48	<0.0001
Cephalic Perimeter-for-Age (CPFA)	153	-1.30 ± 1.14	9.68	129	-1.03 ± 0.9	15.15	0.0314
body mass index-for-age (BMIFA)	153	-0.82 ± 1.33	20.61	129	+0.31 ± 1.3	62.17	<0.0001

- The results demonstrate the impact of Nutralso® on growth and development of infants, illustrating the bioavailability and potential bioactivity of phytonutrients in Nutralso®.
- Nutralso® and its inventors received the Patent for Humanity Award from the U.S. Patent Office in 2013. Subsequently, Sustainable Nutrition International, a non-profit organization in partnership with Quintessence Nutraceuticals was established to further humanitarian initiatives using Nutralso®.



Appendix A: Nutralso® Nutritional Composition

- **Hydrolyzed Proteins** – peptides and amino acids are more bioavailable than complex proteins, possess antioxidant properties, and have additional health benefits including antidiabetic, cholesterol-lowering, antihypertensive, anticancer, and antimicrobial activities
- **Vitamin E (Tocopherols and Tocotrienols)** – fat soluble antioxidants provide positive health benefits in the face of cardiovascular disease, diabetes, cancer and obesity
- **Gamma-oryzanol and Ferulic Acid** – potent antioxidants that lower plasma and serum cholesterol, alleviate postmenopausal syndrome, improve insulin sensitivity, reduce skin related problems and the growth of cancer cells, and stimulate the immune system (rice bran is the primary source for gamma-oryzanol)
- **Vitamins and Minerals** – a balanced profile of vitamins, minerals and micronutrients.



Nutralso® ranks among the highest foods in antioxidant capacity, a key factor in achieving Patent No. 9,192,180 B2 for reducing insulin resistance®.

**Appendix B: Nutralso® Nutritional Profile
(100 gram Analysis)**

Specifications:

Protein	13.1	grams
*(aggregate analysis)		
*Fat	27.9	grams
Saturated	6.4	grams
Trans Fatty Acids	0.0	grams
Polyunsaturated	7.7	grams
Monounsaturated	8.5	grams
*Total Carbohydrates	58.8	grams
*Total Dietary Fiber	21.4	grams
Soluble Fiber	7.1	grams
Insoluble Fiber	14.2	grams
Cholesterol	3	mg
Calories	414	
Calories from Fat	189	
Ash	6.2	grams
Moisture	0.0	grams

Vitamins:

Vitamin A	106.17	mcg
B1 – Thiamin	3.14	mg
B2 – Riboflavin	2.84	mg
B3 – Niacin	7.26	mg
B5 – Pantothenic Acid	6.29	mg
Vitamin B6	3.51	mg
B9 – Folate	126.81	mcg
Vitamin B12	0.64	mcg
C – Ascorbic Acid	10.62	mg
Vitamin D	1.91	mcg
Vitamin E	1.56	mg
Total Tocophenols	2.11	mg
Total Tocotrienols	2.28	mg
Vitamin K	8.08	mcg

Minerals:

Calcium	145.70	mg
Chromium	283.91	mcg
Copper	937.39	mcg
Iron	4.14	mg
Lead	ND	mg
Magnesium	542.30	mg
Manganese	12.95	mg
Molybdenum	35.85	mcg
Phosphorus	1366	mg
Potassium	1.60	grams
Sodium	0.02	grams
Zinc	5.00	mg

Other Nutrients:

Biotin	21.00	mcg
Choline	160.01	mg
Major Phytosterols	481.28	mg
Total Phytosterols	939.88	mg
Gamma-oryzanols	250.34	mg
Ferulic Acid	3502.54	mcg

Antioxidant Levels:

ORAC Hydro	18,604	umole TE
ORAC Lipo	1,892	umole TE
ORAC Total	20,496	umole TE

Appendix C: Nutralso® Patents

U.S. Patent No. 8,945,642 B2

NUTRITIONALLY ENHANCED ISOLATE FROM STABILIZED RICE BRAN AND METHOD OF PRODUCTION

Date of Patent: February 3, 2015

Inventors: Ike E. Lynch, Glenn H. Sullivan, Larry R. Miller

Abstract: Provided is a nutritionally enhanced derivative (isolate) from Stabilized Rice Bran (SRB) with improved antioxidant, fat and protein levels enhancing both the nutritional and yield values over existing techniques. Also provided is an improved method that utilizes certain enzyme combinations under various time and temperature conditions for extracting these nutritionally enhanced isolates from SRB.

In a review of the Nutralso® patent by the USPTO, the examiner concluded that; "(Nutralso®) is a novel rice bran isolate wherein the bulk properties of the protein mixture is "significantly more" than that of the native protein in rice bran... The nutritionally enhanced isolate of (Nutralso®) is a mixture of hydrolyzed protein, hydrolyzed starch and high quality rice bran oil."

Nutralso® was the first to receive a rice bran extraction patent that superseded all prior art.

U.S. Patent No. 9,192,180 B2

NUTRITIONALLY ENHANCED FRACTION FROM RICE BRAN AND METHOD OF LOWERING INSULIN RESISTANCE USING SAME

Date of Patent: November 24, 2015

Inventors: Paul Raymond Reising, Glenn H. Sullivan

Abstract: Nutritionally enhanced nutraceutical hydrophilic and lipophilic Rice Bran Fractions from rice bran are provided as well as a method of using the same to reduce Insulin Resistance in animals, especially humans with pre-diabetes and Type 2 diabetes or others with symptoms of Metabolic Syndrome. Provided in various example embodiments are mixtures of elevated levels of nutraceutical compounds, including but not limited to gamma-oryzanol, inositol, ferulic acid, tocotrienols and phytosterols and pharmaceutical and nutritional compositions thereof. Steps are provided including evaluating insulin resistance parameters, initiating therapy including providing therapeutic amounts of Hydrophilic and Lipophilic Rice Bran Fractions from rice bran to treat prediabetes and Type 2 diabetes or others with symptoms of Metabolic Syndrome, managing compliance with the therapy, and monitoring and reevaluating the therapy.

Nutralso® is the first pure nutraceutical to receive a patent for reducing insulin resistance.

Appendix D: Published Data on Bioavailability Challenges

- Justo et al.(2012) J of Nutritional Biochem 24, 8:1453-1461, concluded: ***“while rice bran is high in nutraceutical nutritional value, including proteins with functional properties, rice bran’s potential use as a functional food supplement was limited by the high insolubility its protein embodiment and nutritional values...particularly related to the phenolic fraction of the bran.”***
- Vallabha et al.(2015) J of Food Sci & Tech 52, 12:8252-8259, concluded that ***“rice bran was found to be a rich source of nutraceutical components and nutrients; however, its utility in human consumption and nutrition was limited due to lipase activity and insolubility.”***
- Justo et al.(2013) Eur J of Nutrition 52, 2:789-797, concluded that ***“therapeutic use of rice bran itself is highly limited due to its insolubility and the breakdown of complex proteins and nutraceutical components within the bran.”***
- Ghazi et al.(2016) Medicinal and Aromatic Plants 5, 5:1-10, concluded: ***“rice bran extracts, not rice bran itself, was found to be effective in blocking salmonella invasion...as compared to stabilized rice bran in laboratory tests.”***