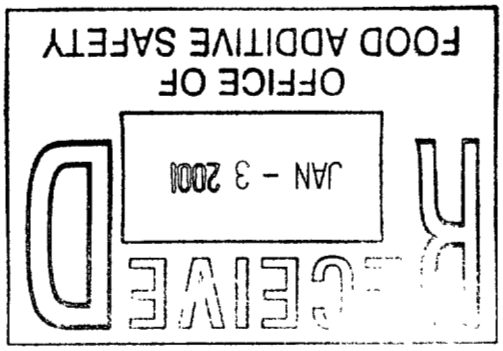
GR 

The New Silk Road, Inc.

cosmetics, skin care, silk protein powder



20 November 2001

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

It is determined by this officer of this company that the SILK PROTEIN FOOD POWDER (full description and anaylsis is enclosed) used as a food ingredient, encapsulated supplement, or by direct consumption in suggested amounts or volume, is exempt from the premarket approval requirements of theFederal Food, Drug andCosmetic Act (the Act) because this officer has determined that such use is GRAS.

The Silk Protein Food Powder is the "notified substance" and this is it usual name. It is 96% pure protein with no additives, no chemicals, no other ingredient.

The notified substance may be consumed in most any amount, but it has suggested levels for different purposes or needs. The usual level is 2-5 grams or a flat teaspoon (5 grams). For fitness and intense activity and for muscle tone or "look good, feel good" muscle, 30 grams is suggested on a daily basis.....this is about 2 tablespoons.

It may be used in or on any food or beverage. The benefits and reasons for its use are described in the enclosed folder.

The numbers of population who may use this protein or who are using any other protein for the same purpose is not known, but is assumed to be perhaps 1 million and more households.

Montpelier, VT 05601
800-722-1419
info@newsilk.com

www.newsilkfood.com
www.miriamgayle.com

The basis for the GRAS determination is based on the use of other proteins in food or as food additives or in food supplements.

All proteins act in similar manner, but some have less fat, and/or less sodium and/or less sugars (carbohydrates) than others. Silk Protein Food Powder has no fat, no cholesterol, no sugar/carbohydrates.

Different proteins have different values as well, especially of amino acids.

Detailed analysis and research determinations are available for the use of the Food and Drug Administration upon its request from this address.

The silk protein powder is extracted from the silk thread of the silk cocoon by a patented hydroylsis process and processed into powder. This is done at the laboratory/processor under the supervision of Dr. Chen patent holder. This lab is located at:

Tiansheng Jie #21
Huzhou, Zhejiang, China

The final process is accomplished by:

Daiwabo Polytech Co., Ltd.
877 Komiya
Harima-cho, Kako-gun,
Hyogo Prefecture, Japan

This process results in almost pure protein (96%). Protein is the basic building element of the body and is found in all vegetable and meat. Without it, the body suffers growth and other factors. Silk protein is merely another protein.....and as noted, each protein differs from another.

Respectfully submitted

Robert G. Averill
Director (i.e., president).
The New Silk Road, Inc.
Montpelier, Vermont 05601

(this is a repeat of a filing of 20 November in single copy in error.....this is to correct that with filing in triplicate).

The New Silk Road, Inc.

cosmetics, skin care, silk protein powder

Health benefits:

1 teaspoon = 10-12 grams
1 tablespoon = 25-30 grams
energy, endurance, muscle tone
may be a brain energizer
provides collagen which prevents liver fat
aids in matabolism of alcohol, thus improves
liver function
silk is fibroin which reduces cholesterol
glycine (amino) in silk protein controls cholesterol
silk protein much more effective in cholesterol control
than any other natural protein.
silk protein is very, very high in glycine
serine controls glucose levels in the liver and muscles
helps strengthen the immune system. effective for
diabetics.
silk protein is very, very high in serine
alanine is source of energy for muscle tissue
silk protein is very, very high in alanine
has blood coagulant properties.....good especially in
dental care for bleeding gums and gingivitis

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www.miriamgayle.com

Dr Kiyoshi Hirabayashi is noted as the foremost authority on silk in food.
Dr Kaili Chen is the researcher and patent holder, under authority of the Japan Silk Association.
He is the Manager of Research and Development of the silk division of the Japan Leisure Development Co., Ltd. (in Japanese, "Leisure development" refers to development of life-style products.....not condominiums).

Quality control and final processing and testing is done by Daiwabo Polytech Co., Ltd. This laboratory is associated with the Japan government.

Purity analysis performed by independent laboratory in Vermont, USA.

We are.

The New Silk Road
Box 105 - Montpelier, VT 05601
1-800-722-1419
www.newsilkfood.com

We are developers and manufacturers of silk products for the cosmetics industry. We know firsthand about the numerous health benefits of cosmetic-quality silk. Our *Miriam Gayle®* line of skin care products makes use of the low molecular weight of silk powders to achieve anti-allergenic benefits for all skin types without the oils and grease normally found in shampoos and creams. Silk-based products provide nutrients to the skin - specifically collagen - and they help relieve the pain and redness of sun (and other) mild burns.

Now, ***edible*** Silk Protein Food Powder is being produced by a complex and patented process. We at New Silk Road, Inc. hold the exclusive sales and marketing rights for this wonderful new product - Silk Protein Food Powder.

There are no animal ingredients in Silk Protein Food Powder. It is not an herb nor a drug. It has blood coagulant properties. At a dosage of 50 grams it is shown to enhance endurance in race horses. Just 2-4 grams a day will produce all potential benefits in humans.

Silk is food, and has been eaten for at least a thousand years. While no specific claims can be made, and results will differ from one person to another, silk provides a unique form of protein that is rich in many valuable nutrients. Our tasteless/odorless powder is easily mixed with any food or beverage to provide a very old, yet very new nutritional protein supplement.

Nutritional Facts

Silk Protein Food Powder offers the:
Highest Amount of Protein (96.9%),
Very High B.V. (96),
Highest P.E.R. (92),
Less Fat (0), Less Cholesterol (0),
Less Carbo (0), Less Sugar (0)

... than any other Protein.

Amino Acids	per 100g
histidine	88.0
isoleucine	157
leucine	137
lysine	49
methionine	<
phenylalanine	177
threonine	432
trytophan	<
analine	942
T Ess Am A	1982
alanine	36100
glycine	45126
proline	117
glutamic acid	736
aspartic acid	1138
cystine	196
tyrosine	667
arginine	39
serine	10300
water%	2.6

900000

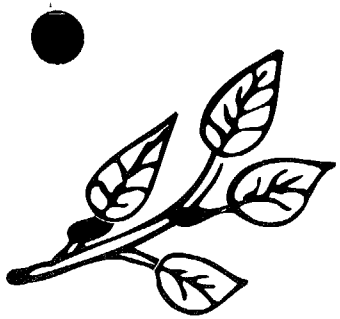
Silk Protein Food Powder

A New Health Food that has been eaten for a Thousand Years!

Fat Free ~ Cholesterol Free
Sugar Free (No Carbohydrates)
Tasteless
Dissolves in any Beverage

Silk Protein Food Powder is FIBROIN... a unique form of protein and a "doma" which when broken down by body enzymes becomes a brain energizer.

Add to most foods at 1% - 3% of the net weight... or, 2-4 grams per day, per person.



Qualities of Silk Protein Food Powder

FIBROIN reduces blood cholesterol levels. Research shows blood cholesterol levels rise rapidly after ingestion of casein protein in food. Replacing only 5% of the casein with silk protein suppresses the rise in cholesterol.

Silk Protein Food Powder has 18 Amino Acids and extremely high levels of the 4 most important aminos:

GLYCINE - helps trigger the release of oxygen for the body's cell-making processes, is a blood cholesterol control, and promotes the metabolism of alcohol thus assisting liver function;

SERINE - is a source of glucose storage in the liver and muscles, and helps to strengthen the immune system;

ALANINE - is an important source of energy for muscle tissue, the brain and the central nervous system, and helps in the metabolism of sugars and organic acids.

ASPARTIC ACID - aids in the expusion of harmful and toxic ammonia from the body. It may also increase resistance to fatigue and increase endurance.

Other Amino Acids present in Silk Protein Powder in moderate quantities are:

TYROSINE - which transmits nerve impulses to the brain and helps to overcome depression, improves memory, and increases mental alertness.

THREONINE - is an important part of collagen - a composition of our body tissues, cartilage and bone - which also helps prevent fat build-up in the liver.

FOOD GRADE SILK POWDER
CHARACTERISTICS: WHITE POWDER, WATER SOLUBLE, ODOR-FREE, SLIGHTLY SWEET TASTE
PH: 4.0-6 0 **WATER:** 2.64% **PROTEIN:** 96.49%
RESIDUALS: 0.87% **FAT:** 0 **ASH:** 0.5%
NITROGEN: 15.8% **SODIUM:** 280 mg/100 gms
ARSENIC: 0 9 ppm **LEAD:** 0.08 ppm
MERCURY: 0 **GENERAL BACILLUS:** 5.9×10^2
MOLECULAR WEIGHT: LESS THAN 300
CALORIES: 400/100 gms **STORAGE:** DUE TO HYGROSCOPIC NATURE, USE PROMPTLY AFTER OPENING. STORE AWAY FROM HIGH HUMIDITY.

P.E.R. (PROTEIN EFFICIENCY RATING): 95
BIOLOGICAL VALUE: 96

AMINO ACID	SIDE CHAIN	SILK SERICINE	SILK FIBROIN
GLYCINE	H	147	445
ALANINE	CH3	43	293
LEUCINE	(CH3) 2CHCH2	14	5
ISOLEUCINE	CH3CH2CH (CH3)	7	7
VALINE	(CH3) 2CH	36	22
PHENYLALANINE	C6H5CH2	3	6
SERINE	CH2OH	373	121
THREONINE	CH3CH(OH)	87	9
ASPARGINIC ACID	HOOCCH2	148	13
GLUTAMIC ACID	HOOCCH2CH2	34	10
ALGININE	NH2C (NH) NH (CH2)3	36	5
CYSTINE	(1/2) (-SCH2) 3	5	2
METHIONINE	CH3SCH2CH2	-	1
LYSINE	NH2 (CH2) 4	24	3
PROLINE	(CH2) 3CHNHCOOH	7	3
HYSTIDINE	N(CH) 2NHCCH2	12	2
TRYPTOPHANE	C6H6NHCH2	-	2
TYROSINE	HOC6H4CH2	26	52
AMMONIA,ETC.		86	-

MANUFACTURERS' SAMPLE OFFER

This is an opportunity to put one or more of *your* products in a unique health / fitness category.
A 250 gram(approx 1/2 lb.), sealed aluminum pouch of silk protein food powder is available for experimental use.
Please fax or post your request with the name of your company and postal or UPS address.
800-722-1419
fax 802-229-1150
email: info@newsilk com

Code 1 00000 2

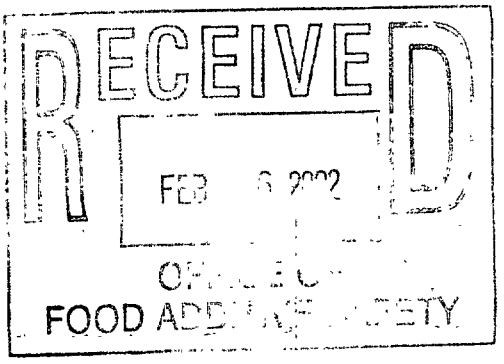
END SUBMISSION

AM

The New Silk Road, Inc.

cosmetics, skin care, silk protein powder

28 January 2002



Kathleen McAveney Jones, Ph.D.
Division of Biotech and GRAS
Notice Review, HFS-206
Center for Food Safety and
Applied Nutrition
Department of Health and Human Services
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835 Re: GRAS Notice No. 000096

Addenda to this submission:

1) relationship between increased insulin levels and blood thinners. Aspirin, for example, acts to keep the blood thin by expanding the blood vessels and by inhibiting platelet coagulation. Insulin's increased output (from silk) is responsible for lowering blood glucose levels, so there is nor relationship between high insulin levels and blood thinners.

2) Cystine is a high molecular weight protein with a very complex structure. Inside a molecule of insulin,cystine is responsible for for making a compound called the "S-S bond". Cystine, therefore, is actually an element of insulin and has no negative effects on insulin's glucose lowering ability.

3) Glycine is immediately turned into ammonia in the body upon ingestion, and this is harmless and normal. The balance of the "urea cycle" and the "glycine cycle" disposes of "free ammonia". People with liver disease do not process these last 2 cycles and, therefore the free ammonia is not removed. This puts an added burden on the liver.

Sincerely

Robert Averill, Director

000011

Montpelier, VT 05601
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www.newsilkfood.com
www.miriamgayle.com

Welcome to IntriguingInsects - the site for weekly news and features for both amateur and professional entomologists alike. Whether the wonderful world of insects frightens or fascinates you, you'll find something of interest here.

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The Story of Silk : Part One - Traditional Methods

by Peter McGrath

The silk moth, *Bombyx mori*, was domesticated by the Chinese over 5000 years ago. Although it can't fly and can no longer survive without the aid of man, because of its precious fibre, it is still spreading around the globe.

This, the first of a two-part IntriguingInsects special, is the story of the silk moth, silkworms and traditional silk production.

Bombyx mori

Legend has it that it was the Chinese Empress Hsi Ling-Shi that 'discovered' silk in 2640 BC. The story goes that she accidentally dropped a silkworm cocoon into her cup of hot tea and, when she tried to remove it, the cocoon unravelled itself revealing a single, long thread.

Recently, however, Chinese archaeologists unearthed a collection of silk cloths and yarn at a Neolithic site. Analysis of the cloth, estimated to have been woven about 2750 BC, indicated that the practice of silk production in China was already well-developed. In other words, the silkworm had already been domesticated.

The silkworm is the larva of the silk moth, *Bombyx mori*. Adult moths have a wingspan of about 4 cm but, due to their large body size, this is not enough to get them airborne. Scientists believe, however, that rapid wing vibrations help to keep the insects warm and may also play a part in the courtship ritual.

Females are generally heavier than males, mainly due to the 300 to 500 eggs they are carrying when they emerge from their pupae.

000012

Traditionally, one brood of eggs is laid, late in the year, and

The Story of Silk : Part Two Biotechnology
intriguinginsects.com

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storytellingpower.com

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americasrevolution.com

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Maggots, Murder and

the silk moth 'strain' is said to be 'univoltine' - i.e. it undergoes one generation a year. Over the centuries, selective breeding programmes have resulted in the development of bivoltine (two generations per year) and multivoltine (several generations per year) strains. Bivoltine strains tend to produce the finest silk which is required for the world market. Multivoltine strains, on the other hand, are preferred in India and produce a coarser fibre, suitable for domestic use in saris etc.

Whatever strain is being grown, sericulture husbandry practices follow the same general rules.

Sericulture

In univoltine strains, the eggs overwinter, hatching when temperatures rise in the spring, coinciding with the first flush of mulberry leaves - the natural host plant of the silk moth caterpillars.

Eggs from bivoltine and multivoltine strains can be stored in the fridge until required. Then, 10 days at 25oC will induce them to hatch. One hatched, the tiny caterpillars must be fed twice a day on fresh mulberry leaves. Not only that, but the age of the leaves must be equivalent to the age of the larvae - fresh, newly expanded leaves for newly-emerged caterpillars, week-old leaves for week-old caterpillars etc. For this reason, the practice of rearing silkworms is closely tied to the practice of mulberry production.

But the caterpillars aren't let loose in the mulberry fields. Centuries of domestication have left them unable to cling to their host plants. Instead, they are kept in bamboo or plastic-netting boxes, stacked on tables in controlled-environment rooms. Nothing is left to chance. The table legs are usually stood in bowls of water to prevent marauding ants climbing up and attacking the defenceless caterpillars.

A room full of chewing silkworms, apparently, makes quite a noise.

After about five weeks of non-stop eating, the caterpillars have increased in length to about 7 or 8 cm and are ready to pupate. At this point, paper, twig or bamboo frames are placed in the boxes to give the caterpillars space to spin their cocoons, a process which takes two whole days.

Pupation takes about a week. However, only the luckiest individuals - usually the heaviest - are selected to reach adulthood. Once they have chewed their way out of their silken cocoons, helped by the production of an enzyme that dissolves sericin (the main silk protein), they are allowed to breed, producing the next generation of silkworms.

The rest of the pupae are less fortunate. They are steamed for three minutes to kill them. Their silk is then 'harvested'.

For pictures of the different life stages of the silk moth, check out this site run by the Moths and Butterflies of Europe people.

Silken statistics

During the two days a silkworm spends spinning its silken cocoon, it will produce, on average, a massive 1300 metres of silk in one continuous strand (one metre is about one yard). To produce one kilogram (2.2 pounds) of silk requires 1500 silkworms which must have been fed with 250 kilograms of mulberry leaves.

World silk production is estimated to be about 60,000 tonnes. By my calculations, that equates to 90,000,000,000 silkworms - or an incredible 117,000,000,000 kilometres (over 73,000,000,000 miles) of silk. If tied end to end to make one 'super-strand', this would be enough silk to wrap around the Earth's equator 3 million times. In fact, it would reach to the farthest point of our solar system, the plant Pluto, and back again.

Silky secrets

Silk is secreted by the caterpillars from two pairs of spinnerets (tubes linked to the silk-producing glands) located on the caterpillar's head. One protein, fibrinogen, is secreted from the posterior part of the gland and, on extrusion, is denatured to fibroin, the protein that makes up the core of each silk filament.

Sericin, the second silk protein, is produced by the middle part of the glands and coats the fibroin. Two filaments, one from each pair of spinnerets, are then spun together by the caterpillar to produce a single fibre.

The silk (and hence the cocoons) can be coloured anything from white through to yellow or pale orange, mainly due to the presence of pigments derived from the mulberry leaves, but this colour is removed during the 'de-gumming' or removal of the sericin. It is this process, perhaps, that has been attributed to the Empress Hsi Ling-Shi.

Sericin is water soluble. Drop a cocoon into some hot water (or a cup of tea) and it will start to unravel. Commercial silk weaving mills use a system of rotating 'brushes' to catch the end of the fibres released from cocoons in a hot water bath. The silk is then simply wound off the cocoon. Each fibre is combined with one or more others to form a thread, held strongly together by the drying sericin. The 'naked' pupae are then disposed of, often by feeding to chickens. Occasionally

they are eaten by people. — A DELICACY IN FRANCE

Despite being composed of fibres of only 3 microns in diameter, silk is incredibly strong. There are reports from the American Wild West of gunfighters being shot, the bullet passing through the fabric of their jackets and, presumably, into their hearts. Silk handkerchiefs placed in their breast pockets, however, were not pierced by the bullets, but remained intact.

The design of the palace of Kubla Khan also testifies to the strength and lightness of silk. It was made of bamboo canes supported by 200 silk cords and could be easily dismantled and moved to a new location if needed. Silk has also been the traditional fibre of choice for surgical sutures.

But above all, it is as the fabric of choice for luxury clothing that silk is best known. The prism-shaped fibres give it a lustrous sheen and it is said to hold coloured dyes better than any other material.

No wonder, then, that the Chinese kept the secret of its production, the silk moth caterpillar, hidden from the western world for so many years. And no wonder that intrepid westerners went to such extraordinary lengths to get their hands on it - developing the Silk Road trading route as they did so.

Even so, the Chinese still lead the world in silk production. Each year, 24 millions boxes of larvae are handed out to 20 million silkworm 'farmers'. Between them, they produce over half the world's supply of silk, worth over $100 million per year. Not bad for a few insects!

Interesting?

If you thought this article was interesting, why not sign up for future editions of IntriguingInsects. Go to the left-hand column and click on "Free Update". If you fill in the information, the weekly IntriguingInsects Newsletter will be emailed to you, giving you details of the latest feature article and insect-related news stories.

Unfortunately, IntriguingInsects has to be funded by advertising. To ensure future editions, please click on one or two of the adverts around this page. You don't have to buy anything - but remember to return to www.intriguinginsects.com.

Also, don't forget the insect vernacular name survey. See the "What's in a name?" article for details.

000015

Did you know?

AM

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cosmetics, skin care, silk protein powder

10 February 2002

Kathleen McAveney Jones, Ph.D.
Division of Biotech and GRAS
Notice Review, HFS-206
Center for Food Safety and
Applied Nutrition
Department of Health and Human Services
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835 Re: GRAS Notice No. 000096

Addenda to this submission:

Silk food protein FLOW CHART, enclosed.

Sincerely

Robert Averill
Director

AMINO ACID	SIDE CHAIN	SILK SERICINE	SILK FIBROIN
GLYCINE	H	147	445
ALANINE	CH3	43	293
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PROLINE	(CH2) 3CHNHCOOH	7	3
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TYROSINE	HOC6H4CH2	26	52
AMMONIA,ETC.		86	-

FOOD GRADE SILK POWDER
CHARACTERISTICS: WHITE POWDER, WATER SOLUBLE, ODOR-FREE, SLIGHTLY SWEET TASTE
PH: 4.0-6.0 **WATER:** 2.64% **PROTEIN:** 96.49%
RESIDUALS: 0.87% **FAT:** 0 **ASH:** 0.5%
NITROGEN: 15.8% **SODIUM:** 280 mg/100 gms
ARSENIC: 0.9 ppm **LEAD:** 0.08 ppm
MERCURY: 0 **GENERAL BACILLUS:** 5.9 x 10^2
MOLECULAR WEIGHT: LESS THAN 300
CALORIES: 400/100 gms **STORAGE:** DUE TO HYGROSCOPIC NATURE, USE PROMPTLY AFTER OPENING. STORE AWAY FROM HIGH HUMIDITY.

P.E.R. (PROTEIN EFFICIENCY RATING): 95
BIOLOGICAL VALUE: 96

Pages 000017 removed under the Privacy Act of 1974.

What's the Problem?

Cholesterol?

Weight?

Energy?

Stamina/endurance?

SilPROtein food from silk has assets that help with these common problems.....

If you are overweight, SilPROtein from silk has 6.7 % of TYROSINE, an amino acid, which is one of the drivers of your metabolism. So, it has an impact on your weight.

SERINE, which SilPROtein has in high percentage (10.30%) is a source of glucose storage in the liver and muscles. So, it helps your system to enhance your insulin sensitivity thus reducing your blood sugar which helps to burn up your stored fat in your body.

Lack energy? Can't seem to keep going at the pace you want to experience? SilPROtein from silk has 36% of ALANINE, an important source of energy for muscle tissue and which helps metabolize sugars and organic acids. TYROSINE and PHENYLALANINE have positive effects on your nervous system.

Cholesterol levels too high? SILK itself is FIBROIN which reduces blood cholesterol levels. SilPROtein has 45% of GLYCINE an important factor in cholesterol control.

What's the Problem?

The relationship between increased insulin levels and blood thinners is nil. Aspirin, a blood thinner, acts to keep the blood thin by inhibiting blood platelet coagulatin. Insulin's increased output from silk is responsible for lowering glucose levels.

Cystine is an element of insulin and has no adverse effects on insulin's glucose lowering ability.

Silk protein helps build muscle from fat.

ALANINE'S 36% content in silk protein is a source of energy for the brain and central nervous system, so it may help to calm nerves.

GLYCINE is immediately upon ingestion converted to ammonia in the body. This is normal and harmless. The balance of the "urea" cycle" and the "glycine cycle" disposes of free ammonia.

ASPARTIC ACID in silk protein at 11% aids in the glycine cycle, helping to resist fatigue and help in stamina/endurance.

SilPROtein from silk has a higher percentage of these amino acids than any other natural protein. It has a digestibilty factor of 92. Eggs factor is 1.00, highest accepted by USF&DA.

Silk protein is 96% protein and there are no other ingredients. It is pure silk from a hydrolysis processing of silk. There are no animal ingredients.

The success of these assets for you depends also on your choice of the foods you eat. If in doubt about food choices please visit your dietician.

SilPRO, Inc. a division of
The New Silk Road, Inc.
Montpelier, Vermont 05601

We a...

The New Silk Road
Box 105 - Montpelier, VT 05601
1-800-722-1419
www.newsilkfood.com

We are developers and manufacturers of silk products for the cosmetics industry. We know firsthand about the numerous health benefits of cosmetic-quality silk. Our *Miriam Gayle®* line of skin care products makes use of the low molecular weight of silk powders to achieve anti-allergenic benefits for all skin types without the oils and grease normally found in shampoos and creams. Silk-based products provide nutrients to the skin - specifically collagen - and they help relieve the pain and redness of sun (and other) mild burns.

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Silk is food, and has been eaten for at least a thousand years. While no specific claims can be made, and results will differ from one person to another, silk provides a unique form of protein that is rich in many valuable nutrients. Our tasteless/odorless powder is easily mixed with any food or beverage to provide a very old, yet very new nutritional protein supplement.

Nutritional Facts

Silk Protein Food Powder offers the:
Highest Amount of Protein (96.9%),
Very High B.V. (96),
Highest P.E.R. (92),
Less Fat (0), Less Cholesterol (0),
Less Carbo (0), Less Sugar (0)

... than any other Protein.

Amino Acids	per 100g	%
histidine	88.0	.09
isoleucine	157	.16
leucine	137	.14
lysine	49	.05
methionine	<	
phenylalanine	177	.18
threonine	432	.43
trytophan	<	
analine	942	.94
T Ess Am A	1982	2.00
alanine	36100	36.0
glycine	45126	45.0
proline	117	.12
glutamic acid	736	.74
aspartic acid	1138	1.14
cystine	196	.20
tyrosine	667	.67
arginine	39	.40
serine	10300	10.0
water%	2.6	

020000

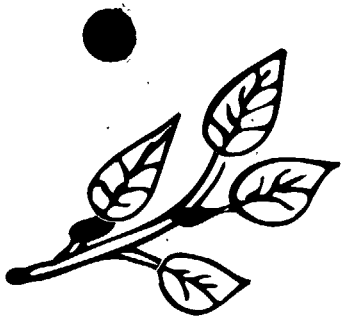
Silk Protein Food Powder

A New Health Food that has been eaten for a Thousand Years!

Fat Free ~ Cholesterol Free
Sugar Free (No Carbohydrates)
Tasteless
Dissolves in any Beverage

Silk Protein Food Powder is FIBROIN... a unique form of protein and a "doma" which when broken down by body enzymes becomes a brain energizer.

Add to most foods at 1% - 3% of the net weight... or, 2-4 grams per day, per person.



Qualities of Silk Protein Food Powder

FIBROIN reduces blood cholesterol levels. Research shows blood cholesterol levels rise rapidly after ingestion of casein protein in food. Replacing only 5% of the casein with silk protein suppresses the rise in cholesterol.

Silk Protein Food Powder has 18 Amino Acids and extremely high levels of the 4 most important aminos:

GLYCINE - helps trigger the release of oxygen for the body's cell-making processes, is a blood cholesterol control, and promotes the metabolism of alcohol thus assisting liver function;

SERINE - is a source of glucose storage in the liver and muscles, and helps to strengthen the immune system;

ALANINE - is an important source of energy for muscle tissue, the brain and the central nervous system, and helps in the metabolism of sugars and organic acids.

ASPARTIC ACID - aids in the expusion of harmful and toxic ammonia from the body. It may also increase resistance to fatigue and increase endurance.

Other Amino Acids present in Silk Protein Powder in moderate quantities are:

TYROSINE - which transmits nerve impulses to the brain and helps to overcome depression, improves memory, and increases mental alertness.

THREONINE - is an important part of collagen - a composition of our body tissues, cartilage and bone - which also helps prevent fat build-up in the liver.

MANUFACTURERS' SAMPLE OFFER

This is an opportunity to put one or more of *your* products in a unique health / fitness category.
A 250 gram(approx 1/2 lb.), sealed aluminum pouch of silk protein food powder is available for experimental use.
Please fax or post your request with the name of your company and postal or UPS address.
800-722-1419
fax 802-229-1150
email: info@newsilk.com

000021

FOOD GRADE SILK POWDER
CHARACTERISTICS: WHITE POWDER, WATER SOLUBLE, ODOR-FREE, SLIGHTLY SWEET TASTE
PH: 4.0-6.0 **WATER:** 2.64% **PROTEIN:** 96.49%
RESIDUALS: 0.87% **FAT:** 0 **ASH:** 0.5%
NITROGEN: 15.8% **SODIUM:** 280 mg/100 gms
ARSENIC: 0.9 ppm **LEAD:** 0.08 ppm
MERCURY: 0 **GENERAL BACILLUS:** 5.9×10^2
MOLECULAR WEIGHT: LESS THAN 300
CALORIES: 400/100 gms **STORAGE:** DUE TO HYGROSCOPIC NATURE, USE PROMPTLY AFTER OPENING. STORE AWAY FROM HIGH HUMIDITY.

P.E.R. (PROTEIN EFFICIENCY RATING): 95
BIOLOGICAL VALUE: 96

AMINO ACID	SIDE CHAIN	SILK SERICINE	SILK FIBROIN
GLYCINE	H	147	445
ALANINE	CH3	43	293
LEUCINE	(CH3) 2CHCH2	14	5
ISOLEUCINE	CH3CH2CH (CH3)	7	7
VALINE	(CH3) 2CH	36	22
PHENYLALANINE	C6H5CH2	3	6
SERINE	CH2OH	373	121
THREONINE	CH3CH(OH)	87	9
ASPARGINIC ACID	HOOCCH2	148	13
GLUTAMIC ACID	HOOCCH2CH2	34	10
ALGININE	NH2C (NH) NH (CH2)3	36	5
CYSTINE	(1/2) (-SCH2) 3	5	2
METHIONINE	CH3SCH2CH2	-	1
LYSINE	NH2 (CH2) 4	24	3
PROLINE	(CH2) 3CHNHCOOH	7	3
HYSTIDINE	N(CH) 2NHCCH2	12	2
TRYPTOPHANE	C6H6NHCH2	-	2
TYROSINE	HOC6H4CH2	26	52
AMMONIA,ETC.		86	-

AM

The New Silk Road, Inc.
800-722-1419 Info@newsilk.com
802-229-1150 fax

28 February 2002

Kathleen McAveney Jones, PhD
Division of Biotech and GRAS
Notice Review, HFS-206
Center for Food Safety and Applied Nutrition
Department of Health and Human Services
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835 Re: GRAS Notice 000096

Dear Dr Jones,

The enclosed papers are to replace the same pages sent to you on 10 February.

The papers on 10 February were single...not in 3 copies.

These papers enclosed are 3 copies each.

Sincerely

Robert Averni
Director

Jones, Kathleen

From:
Sent: Friday, June 14, 2002 8:00 AM
To: Jones, Kathleen
Subject: 000096

SU

SilPRO, Inc./div The New Silk Road, Inc.
POBox 105, Montpelier, VT 05601
800-722-1419 fax 802-229-1150

Dr Kathleen McAveney Jones, Ph.D.
Division of Biotech and GRAS Notice Review. HFS 206

We have the letter critique from Dr Alan M. Rulis ref our lack of properly organized material and scientific evidence.

A new application will be submitted under this file 000096.

In our original application we submitted a FLOW CHART indicating the process, step-by-step, of developing our silk food protein. This also described the actual materials used in this process. This is proprietary information which, at the time, we believed was required in the application.

Is it possible that this page can be removed from our "not approved" file and destroyed? It is our understanding that this information is not removable in approved and permanent files.

Thank you for your kind attention.
Sincerely
Robert Averill
Director

000040

6/14/2002

SilPROtein, the superior new food protein

SU

27 June 2002

Kathleen McAveney Jones, Ph.D.
Division of Biotech and GRAS
Notice Review, HFS-206
Center for Food Safety
and Applied Nutrition
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

GRAS Notice 000096

Dear Dr. Jones,

I enclose herein a completely new application for GRAS notification for SILK FOOD PROTEIN POWDER.

Supporting technical and research information and material is attached.

Sincerely,

Robert Averill
Director

SilPRO, Inc., a division of The New Silk Road, Inc.
POBox 105, Montpelier, VT 05601 + info@newsilk.com
800-722-1419 + www.newsilkfood.com
ISO9001/JISZ9901/BSENISO9001

000041

SilPROtein, the superior new food protein

27 June 2002

U.S. Food & Drug Administration
Office of Premarket Approval
Center for Food Safety and Applied Nutrition
Division of Biotech and GRAS Notice Review, HFS-206
5100 Paint Branch Parkway
College Park, MD 20740-3835

re: GRAS Notice 000096

The SilPRO, Inc. company, a division of The New Silk Road, Inc. company (both are Vermont corporations) re-submits, with new information, its claim that the use of SILK FOOD PROTEIN POWDER is exempt from premarket approval requirements of the Federal Food, Drug and Cosmetic Act (the Act) because the company has determined that such use is GRAS.

A definition: in the term of "silk" the powder = peptide. Please see page 2, paragraph 1 of "Results and Discussion" of "Research Leading to SILK FIBROIN PROTEIN as a food ingredient/additive/product", attached.

SILK FOOD PROTEIN POWDER is a development of research by Drs Kaili Chen and Kiyoshi Hirabayashi resulting from a request of the Japan Silk Association.

Such research has resulted in a patented process for the refinement of virgin excess silk ("excess"= silk not used from the silk thread unwinding of the silk cocoon for textile or cosmetic use) to food quality.

While silk has been eaten by silk farm workers and others for over 1000 years, it is not, in its harvested form, an easily digestible product and so not eaten generally by the public.

The process resulting from this research has developed a 92% digestiblity index in a fine powder form.

SilPRO, Inc., a division of The New Silk Road, Inc.
POBox 105, Montpelier, VT 05601 + info@newsilk.com
800-722-1419 + www.newsilkfood.com
ISO9001/JISZ9901/BSENISO9001

The powder is used in the manufacture of foods such as pastas, candies, baked goods, cereals, fitness beverages and candy bars, in capsule or tablet form as a food or dietary supplement by itself or in combination with other ingredients such as vitamins or minerals.

It is used in these products on the ratio of 2%-5% of the net weight of the product. It does not change the product in anyway, but adds the assets of the silk food protein (see "Amino Acids").

Silk food protein is also used as a household food supplement by itself at the rate of 5 grams (one teaspoon) daily for the average person in breakfast beverages, or on cereals, etc.

a) it should be noted that SILK PROTEIN FOOD POWDER has an efficacy or effectiveness greater than any other extracted or processed protein.

1) for example:

a recent report of the US Food & Drug Administration quoted in a monthly paper "Environmental Nutrition" states that "for soy to claim that it may reduce the risk of heart disease when included in a diet low in both saturated fat and cholesterol..../....to carry the claim, a food must contain at least 6.25 grams of soy protein per serving. That is one quarter of the 25 grams a day believed needed to lower cholesterol. Four servings of soy a day will lower LDL's about 5% to 7%....."

SILK PROTEIN requires 60% of the soy requirement. Please see attached "Research Leading To SILK FIBROIN PROTEIN as a food ingredient/additive/product", Section 2, at the bottom of page 4.

In Japan, its origin country, consumption of SILK FOOD PROTEIN POWDER foods has reached perhaps a population of a few million people.

a) in Asian countries cosmetic grade silk protein has been and is used in similar foods....baked, pasta, etc. and has been so used for hundreds of years. Silk itself has been used in fabric for 4000 years.

1) cosmetic grade silk varies from 8% to 13% nitrogen content and is not processed by the same method as today's food grade.

SILK FOOD PROTEIN POWDER is used extensively in Japan by food manufacturers and processors in foods described above, and by resorts, hotels and spas in hand-made candies for guests or as a food/dietary supplement for those who wish it, or as part of a spa program diet.

In the United States, consumption is less than 1000 people, simply because the product is beginning to be introduced to food manufacturers at this point in time. It is also being introduced in Thailand by this company and in the UK.

Some recognized food manufacturers in Europe are working with the silk protein powder to determine a formula for their use.

The company determines that silk food protein powder is GRAS based on the consumption pattern and experience in Japan, and on scientific evidence presented herein as addenda to this application.

SILK FOOD PROTEIN POWDER is the full and complete substance and has no other ingredients, chemicals or additives. It is from the cocoon of the silk moth, a cultivated variety of the silk moth which has been domesticated and commercially raised in China for several hundreds of years and today does not otherwise exist in its natural state (in the same sense that dogs and cats as human pets no longer exist in their natural state). The silk moth feeds on the leaves of the white mulberry. There are no animal ingredients in SILK FOOD PROTEIN POWDER.

SILK FOOD PROTEIN POWDER is processed by either of two methods.....hydrolysis or enzyme separation.

The company laboratories at a Shanghai university and the final processing laboratory in Tokyo (see attached) use the enzyme separation method with a particular enzyme whose origin is in the United States.

Attached to this letter is an outline of the specifications and characteristics of SILK FOOD PROTEIN POWDER, including the respective values of amino acids contained therein.

Silk Food Protein Powder contains:

no fat	no lactose
no cholesterol	no gluten
no sugar	no casein
no carbohydrate	

It contains 18 amino acids (see attached table of specifications).

It is believed by the researchers (Dr Hirabayashi is reputed to be the primary world authority on silk) that there are no limiting factors to the human consumption of SILK FOOD PROTEIN POWDER, other than common sense. Drs Chen and Hirabayashi suggest, however,

that consumption be limited to 30-50 grams daily (an amount beyond the need for any human other than the extreme athlete) for reason that some amino acids may be excessive otherwise.

Amino acids are a component of all proteins, but in varying and different amounts and percentages and all vegetable and animal matter is protein. We are protein ourselves.

The Tokyo laboratory is ISO9001/JISZ9901/BSENISO9001 accredited.

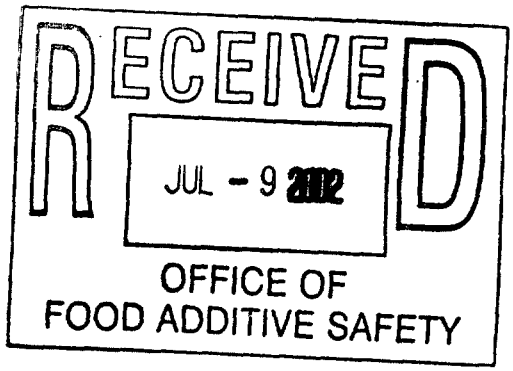
There are no known adverse reports or investigations of silk or of silk food protein. Silk is perhaps the oldest known natural substance that has been used in textiles, cosmetics and food (other than animals found in the prehistoric wild and used for food and body cover).

It is believed and ascertained from all evidence available that silk protein powder for food is as safe as any other accepted food protein and is, therefore, GRAS.

Respectfully submitted

Robert Averill
Director

SilPROtein, the superior new food protein



2 July 2002

Specifications and amino acid profile of silk food protein powder were prepared by Japan Food Research Laboratories, a quasi-government laboratory.

We believe the Food & Drug Administration is familiar with this laboratory because most, if not all Japanese food companies requesting F&DA certification or notification use this laboratory.

Robert Averill
for SilPRO, Inc.

000046

SilPRO, Inc., a division of The New Silk Road, Inc.
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ISO9001/JISZ9901/BSENISO9001

Qualities of Silk Protein Food Powder

FIBROIN reduces blood cholesterol levels. Research shows blood cholesterol levels rise rapidly after ingestion of casein protein in food. Replacing only 5% of the casein with silk protein suppresses the rise in cholesterol.

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GLYCINE - helps trigger the release of oxygen for the body's cell-making processes, is a blood cholesterol control, and promotes the metabolism of alcohol thus assisting liver function;

SERINE - is a source of glucose storage in the liver and muscles, and helps to strengthen the immune system;

ALANINE - is an important source of energy for muscle tissue, the brain and the central nervous system, and helps in the metabolism of sugars and organic acids.

ASPARTIC ACID - aids in the expusion of harmful and toxic ammonia from the body. It may also increase resistance to fatigue and increase endurance.

Other Amino Acids present in Silk Protein Powder in moderate quantities are:

TYROSINE - which transmits nerve impulses to the brain and helps to overcome depression, improves memory, and increases mental alertness.

THREONINE - is an important part of collagen - a composition of our body tissues, cartilage and bone - which also helps prevent fat build-up in the liver.

FOOD GRADE SILK POWDER
CHARACTERISTICS: WHITE POWDER, WATER SOLUBLE, ODOR-FREE, SLIGHTLY SWEET TASTE
PH: 4.0-6.0 **WATER:** 2.64% **PROTEIN:** 96.49%
RESIDUALS: 0.87% **FAT:** 0 **ASH:** 0.5%
NITROGEN: 15.8% **SODIUM:** 280 mg/100 gms
ARSENIC: 0.9 ppm **LEAD:** 0.08 ppm
MERCURY: 0 **GENERAL BACILLUS:** 5.9×10^2
MOLECULAR WEIGHT: LESS THAN 300
CALORIES: 400/100 gms **STORAGE:** DUE TO HYGROSCOPIC NATURE, USE PROMPTLY AFTER OPENING. STORE AWAY FROM HIGH HUMIDITY.

P.E.R. (PROTEIN EFFICIENCY RATING): 95
BIOLOGICAL VALUE: 96

AMINO ACID	SIDE CHAIN	SILK SERICINE	SILK FIBROIN
GLYCINE	H	147	445
ALANINE	CH3	43	293
LEUCINE	(CH3) 2CHCH2	14	5
ISOLEUCINE	CH3CH2CH (CH3)	7	7
VALINE	(CH3) 2CH	36	22
PHENYLALANINE	C6H5CH2	3	6
SERINE	CH2OH	373	121
THREONINE	CH3CH(OH)	87	9
ASPARGINIC ACID	HOOCCH2	148	13
GLUTAMIC ACID	HOOCCH2CH2	34	10
ALGININE	NH2C (NH) NH (CH2)3	36	5
CYSTINE	(1/2) (-SCH2) 3	5	2
METHIONINE	CH3SCH2CH2	-	1
LYSINE	NH2 (CH2) 4	24	3
PROLINE	(CH2) 3CHNHCOOH	7	3
HYSTIDINE	N(CH) 2NHCCH2	12	2
TRYPTOPHANE	C6H6NHCH2	-	2
TYROSINE	HOC6H4CH2	26	52
AMMONIA,ETC.		86	-

SilPRO, Inc.
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info@newsilk.com
802-229-1006 / 800-722-1419

SilPROtein, the superior new food protein

PROTEIN NUTRITIONAL COMPARATIVE ANALYSIS

Values	**silk**	SOY	Skim MILK	Large EGG	WHEY	Lean BEEF	Sole FISH	Breast CHICKEN
Protein (BV)	96	59	91	100	104	80	83	79
Protein % = g/100	96.9			3.4	12.5	12.9	18.7	18.8
Fat (g)	0	.5	1.6	10.8	1.13	17	9	1.24
Saturated Fat (g)	0			.12	3.1	.63	6.8	.28
Cholesterol (mg)	0	.31	5	426	0	69	47.9	57.6
Calories kc	4	200	35	150	350	235	91	109
kj		358	147	628	1464	981	382	457
Amino Acids	See accompanying chart							
Carbohydrate	0	3.8	5.1	0	61	0	0	0
Lactose	0	0				0	0	0
P.E.R.	92	2.2		3.8	3.2	2.9		
PDCAAS	92					1.14		
Water %	2.6	14	75	75	93	53	78	69
Sodium (mg)	2.8	2.8	1	140		45	101	60
Gluten	There is no gluten in these foods							
Casein	0	0	75.3			0	0	0

BV = biological value
P.E.R. = protein efficiency rating
PDCAAS = protein digestibility corrected amino acid score

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Silk Protein Food Powder offers the:
Highest Amount of Protein (96.9%),
Very High B.V. (96),
Highest P.E.R. (92),
Less Fat (0), Less Cholesterol (0),
Less Carbo (0), Less Sugar (0)

... than any other Protein.

Amino Acids	per 100g
histidine	88.0
isoleucine	157
leucine	137
lysine	49
methionine	<
phenylalanine	177
threonine	432
trytophan	<
Valine	942
T Ess Am A	1982
alanine	36100
glycine	45126
proline	117
glutamic acid	736
aspartic acid	1138
cystine	196
tyrosine	667
arginine	39
serine	10300
water%	2.6

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802-229-1006 / 800-722-1419

SilPRO, Inc.
Food Silk Protein Powders

Silk Amino Acids

Overview

AMINO ACIDS are the "building blocks" of the body. Besides building cells and repairing tissue, they form antibodies to combat invading bacteria & viruses; they are part of the enzyme & hormonal system; they build nucleoproteins (RNA & DNA); they carry oxygen throughout the body and participate in muscle activity. When protein is broken down by digestion the result is 22 known amino acids. Eight are essential (cannot be manufactured by the body) the rest are non-essential (can be manufactured by the body with proper nutrition).

TRYPTOPHAN (Essential Amino Acid)
A natural relaxant, helps alleviate insomnia by inducing normal sleep; reduces anxiety & depression; helps in the treatment of migraine headaches; helps the immune system; helps reduce the risk of artery & heart spasms; works with Lysine in reducing cholesterol levels.

LYSINE (Essential Amino Acid)
Insures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissues); aids in the production of antibodies, hormones & enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems.

METHIONINE (Essential Amino Acid)
Is a principle supplier of sulfur which prevents disorders of the hair, skin and nails; helps lower cholesterol levels by increasing the liver's production of lecithin; reduces liver fat and protects the kidneys; a natural chelating agent for heavy metals; regulates the formation of ammonia and creates ammonia-free urine which reduces bladder irritation; influences hair follicles and promotes hair growth.

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SilPRO, Inc.
Silk Amino Acids

PHENYLALAINE (Essential Amino Acid)
Used by the brain to produce Norepinephrine, a chemical that transmits signals between nerve cells and the brain; keeps you awake and alert; reduces hunger pains; functions as an antidepressant and helps improve memory.

THREONINE (Essential Amino Acid)
Is an important constituent of collagen, Elastin, enamel protein; helps prevent fat build-up in the liver; helps the digestive and intestinal tracts function more smoothly; assists metabolism and assimilation.

VALINE (Essential Amino Acid)
Promotes mental vigor, muscle coordination and calm emotions.

LEUCINE & ISOLEUCINE (Essential Amino Acid)
They provide ingredients for the manufacturing of other essential biochemical components in the body, some of which are utilized for the production of energy, stimulants to the upper brain and helping you to be more alert.

ARGININE (Non-Essential Amino Acid)
Studies have shown that it has improved immune responses to bacteria, viruses & tumor cells; promotes wound healing and regeneration of the liver; causes the release of growth hormones; considered crucial for optimal muscle growth and tissue repair.

TYROSINE (Non-Essential Amino Acid)
Transmits nerve impulses to the brain; helps overcome depression; improves memory; increases mental alertness; promotes the healthy functioning of the thyroid, adrenal and pituitary glands.

GLYCINE (Non-Essential Amino Acid)
Helps trigger the release of oxygen to the energy requiring cell-making process; important in the manufacturing of hormones responsible for a strong immune system.

SERINE (Non-Essential Amino Acid)
A storage source of glucose by the liver and muscles; helps strengthen the immune system by providing antibodies; synthesizes fatty acid sheath around nerve fibers.

SilPRO, Inc.
Silk Amino Acids

GLUTAMIC ACID (Non-Essential Amino Acid)
Considered to be nature's "Brain food" by improving mental capacities; helps speed the healing of ulcers; gives a "lift" from fatigue; helps control alcoholism, schizophrenia and craving for sugar.

ASPARTIC ACID (Non-Essential Amino Acid)
Aids in the expulsion of harmful ammonia from the body. When ammonia enters the circulatory system it acts as a highly toxic substance which can be harmful to the central nervous system. Recent studies have shown that Aspartic Acid may increase resistance to fatigue and increase endurance.

TAURINE (Non-Essential Amino Acid)
Helps stabilize the excitability of membranes which is very important in the control of epileptic seizures. Taurine and sulfur are considered to be factors necessary for the control of many biochemical changes that take place in the aging process; aids in the clearing of free radical wastes.

CYSTINE (Non-Essential Amino Acid)
Functions as an antioxidant and is a powerful aid to the body in protection against radiation and pollution. It can help slow down the aging process, deactivate free radicals, neutralize toxins, aids in protein synthesis and presents cellular change. It is necessary for the formation of the skin, which aids in recovery from burns and surgical operations. Hair and skin are made up 10-14% Cystine.

HISTIDINE (Non-Essential Amino Acid)
Is found abundantly in hemoglobin; has been used in the treatment of rheumatoid arthritis, allergic diseases, ulcers & anemia. A deficiency can cause poor hearing.

PROLINE (Non-Essential Amino Acid)
Is extremely important for the proper functioning of joints and tendons; also helps maintain and strengthen heart muscles.

ALANINE (Non-Essential Amino Acid)
Is an important source of energy for muscle tissue, the brain and central nervous system; strengthens the immune system by producing antibodies; helps in the metabolism of sugars and organic acids.

000053-001

Pages 000054-000061 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000062-000066 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

November 22, 2002

Robert Averill
SilPRO Inc.
P.O. Box 105
Montpelier, VT 05601

Re: Silk Protein Hydrolysate

Dear Mr. Averill:

The Food and Drug Administration (FDA) is not filing the notice dated June 27, 2002, that you submitted on behalf of SilPRO, Inc. (SilPRO) under the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received your notice on July 9, 2002.

You describe the subject of SilPRO's notice by various terms, including silk protein food powder, silk food protein powder, food silk protein powder, silk fibroin powder, and food grade silk powder. For the purpose of this letter, we are describing the subject of SilPRO's notice as "silk protein hydrolysate." The notice informs FDA of the view of SilPRO that silk protein hydrolysate is GRAS for use as a source of protein.

In a previous notice dated November 20, 2001, which you submitted on behalf of The New Silk Road, Inc. (New Silk Road), you informed FDA of view of New Silk Road that the use of silk fibroin protein food powder is GRAS for use in food as a protein source. FDA received the notice on January 3, 2002, filed it on January 3, 2002, and designated it as GRAS Notice No. GRN 000096. FDA responded to GRN 000096 by letter dated May 20, 2002 (Ref. 1). In that letter, FDA concluded that GRN 000096 did not provide a sufficient basis for a GRAS determination, largely for failure to provide all required elements of a GRAS notice according to proposed 21 CFR 170.36.

In a petition dated October 6, 2001, you requested that FDA approve silk protein powder for use as a food additive. FDA responded to that petition by letter, dated November 26, 2001, explaining that the information you provided did not constitute a petition suitable for filing. We have enclosed a copy of FDA's letter dated November 26, 2001, because aspects of that letter also pertain to your present submission.

As discussed more fully below, your notice dated June 27, 2002, fails to support a conclusion that silk protein hydrolysate is GRAS. Because our conclusion about your new notice is no different than our conclusion about GRN 000096, we are not filing your new notice as a GRAS notice.

Information provided in your submission dated June 27, 2002

Your submission dated June 27, 2002, provides more information about silk protein hydrolysate than you provided in GRN 000096. Your submission consists of a letter; a four page narrative; a one page statement about the laboratory that provided the specifications for, and the amino acid profile of, silk protein hydrolysate; six pages that include specifications, a list of amino acid contents, descriptions of dietary attributes of the amino acids found in silk protein hydrolysate, and information comparing composition of silk protein to other proteinaceous foods; and two apparently unpublished manuscripts on studies relating to the use of silk fibroin protein as a food ingredient.

In general, the descriptions of procedures to be used in manufacturing the silk protein hydrolysate are incomplete and inadequate. FDA's letter dated November 26, 2001 previously stated concerns about the safety of the manufacturing process. The current submission states that silk protein hydrolysate "is processed by either of two methods.... hydrolysis or enzyme separation." Some information on preparing an acid hydrolysate is provided in the experimental procedures in the appended scientific manuscript (J. Luo, K. Chen, Q. Xu and K. Hirabayashi, "Study on foodization [sic] of fibroin and its functionality"). Degumming and hydrolysis is also described generally in a second manuscript (K. Hirabayashi, K. Chem, D. Akiyama, and Z Ayub, "Applications of excess silk"). However, you provide this information only as general descriptions within experimental protocols rather than as standardized manufacturing procedures that have been used consistently and incorporate good manufacturing practices. While enzymatic hydrolysis is specified as an alternative, your notice provides no information about the enzymes used, the conditions of their use, or other steps in production of the protein hydrolysate. Further, on page 1, you describe a "patented process," but fail to disclose details of that process.

Dietary intake

Your narrative lists conventional foods in which the silk protein hydrolysate would be used, and indicates it would be used at 2-5 percent of the net weight of the product, but does not estimate what the total intake would be from this consumption. Your estimate that consumption of silk protein hydrolysate from its use in dietary supplements would be 5 grams (g) daily does not address the actual subject of your submission - i.e., consumption of the ingredient in conventional foods.

Quality and quantity of information to support a conclusion that the intended use of silk protein hydrolysate is GRAS through scientific procedures

Under 21 CFR 170.30(a), "General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."

Your submission asserts that the basis for SilPRO's view that silk protein hydrolysate is GRAS includes scientific procedures. However, you have provided little or no information to support

that view. Under 21 CFR 170.30(b), "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information." In the narrative that SilPRO provides, SilPRO neither cites references to published information (in general, peer-reviewed scientific literature) about the identity, method of manufacture, and safety of silk protein hydrolysate nor describes the basis for SilPRO's conclusion that qualified experts have evaluated such generally available data and information and concluded that these data and information are adequate to establish safety. Rather, your narrative largely provides anecdotal descriptions of current consumption in Japan. This does not meet the standards described in 21 CFR 170.30(b).

Alternative view that the intended use of silk protein hydrolysate is GRAS through experience based on common use in food

Your submission also asserts that the basis for SilPRO's view that silk protein hydrolysate is GRAS includes experience based on common use in food. However, you have provided little or no information to support that view. Under 21 CFR 170.3 (f), "Common use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Further, under 21 CFR 170.30 (c)(2) "Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance." You have provided no such information or documentation in your submission. The unattributed statements in your submission (e.g., "while silk has been eaten by silk farm workers and others for over 1000 years...", or "Silk Food Protein Powder is used extensively in Japan by food manufacturers and processors....") do not serve as documentation of this use.

Conclusions

We have added a copy of your submission dated June 27, 2002, on behalf of SilPRO to the administrative file for GRN 000096.

We recommend that you review the agency's discussion, in the GRAS proposal, of the scientific, legal, and regulatory underpinnings of the GRAS notification program. In particular, we recommend that you review the agency's discussion of the differences between a food additive and a GRAS substance. As discussed in that proposal (62 FR 18940), a determination that a particular use of a substance is GRAS requires technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted by qualified experts. In contrast, authorization of a particular use of a substance as a food additive requires technical evidence of safety and review and approval by FDA. For this reason, we also recommend that you review the information on the home page of the Office of Food Additive Safety regarding the food additive petition process (Ref. 2). As a reminder, FDA's letter dated November 26, 2001, discusses some data and information that might be appropriate for inclusion in a food additive petition.

Sincerely,

Robert I. Merker, Ph.D.
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

References

1. Letter dated May 20, 2001, from Alan Rulis of FDA to Robert Averill. Available at http://www.cfsan.fda.gov/~lrd/foodadd.html.

2. A series of guidance documents are available at http://vm.cfsan.fda.gov/~lrd/foodadd.html

DEPARTMENT OF HEALTH AND HUMAN SERVICES

November 22, 2002

Robert Averill
SilPRO Inc.
P.O. Box 105
Montpelier, VT 05601

Re: Silk Protein Hydrolysate

Dear Mr. Averill:

The Food and Drug Administration (FDA) is not filing the notice dated June 27, 2002, that you submitted on behalf of SilPRO, Inc. (SilPRO) under the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received your notice on July 9, 2002.

You describe the subject of SilPRO's notice by various terms, including silk protein food powder, silk food protein powder, food silk protein powder, silk fibroin powder, and food grade silk powder. For the purpose of this letter, we are describing the subject of SilPRO's notice as "silk protein hydrolysate." The notice informs FDA of the view of SilPRO that silk protein hydrolysate is GRAS for use as a source of protein.

In a previous notice dated November 20, 2001, which you submitted on behalf of The New Silk Road, Inc. (New Silk Road), you informed FDA of view of New Silk Road that the use of silk fibroin protein food powder is GRAS for use in food as a protein source. FDA received the notice on January 3, 2002, filed it on January 3, 2002, and designated it as GRAS Notice No. GRN 000096. FDA responded to GRN 000096 by letter dated May 20, 2002 (Ref. 1). In that letter, FDA concluded that GRN 000096 did not provide a sufficient basis for a GRAS determination, largely for failure to provide all required elements of a GRAS notice according to proposed 21 CFR 170.36.

In a petition dated October 6, 2001, you requested that FDA approve silk protein powder for use as a food additive. FDA responded to that petition by letter, dated November 26, 2001, explaining that the information you provided did not constitute a petition suitable for filing. We have enclosed a copy of FDA's letter dated November 26, 2001, because aspects of that letter also pertain to your present submission.

As discussed more fully below, your notice dated June 27, 2002, fails to support a conclusion that silk protein hydrolysate is GRAS. Because our conclusion about your new notice is no different than our conclusion about GRN 000096, we are not filing your new notice as a GRAS notice.

000071

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
DBGNE		11/22/02						

Information provided in your submission dated June 27, 2002

Your submission dated June 27, 2002, provides more information about silk protein hydrolysate than you provided in GRN 000096. Your submission consists of a letter; a four page narrative; a one page statement about the laboratory that provided the specifications for, and the amino acid profile of, silk protein hydrolysate; six pages that include specifications, a list of amino acid contents, descriptions of dietary attributes of the amino acids found in silk protein hydrolysate, and information comparing composition of silk protein to other proteinaceous foods; and two apparently unpublished manuscripts on studies relating to the use of silk fibroin protein as a food ingredient.

In general, the descriptions of procedures to be used in manufacturing the silk protein hydrolysate are incomplete and inadequate. FDA's letter dated November 26, 2001 previously stated concerns about the safety of the manufacturing process. The current submission states that silk protein hydrolysate "is processed by either of two methods.... hydrolysis or enzyme separation." Some information on preparing an acid hydrolysate is provided in the experimental procedures in the appended scientific manuscript (J. Luo, K. Chen, Q. Xu and K. Hirabayashi, "Study on foodization [sic] of fibroin and its functionality"). Degumming and hydrolysis is also described generally in a second manuscript (K. Hirabayashi, K. Chem, D. Akiyama, and Z Ayub, "Applications of excess silk"). However, you provide this information only as general descriptions within experimental protocols rather than as standardized manufacturing procedures that have been used consistently and incorporate good manufacturing practices. While enzymatic hydrolysis is specified as an alternative, your notice provides no information about the enzymes used, the conditions of their use, or other steps in production of the protein hydrolysate. Further, on page 1, you describe a "patented process," but fail to disclose details of that process.

Dietary intake

Your narrative lists conventional foods in which the silk protein hydrolysate would be used, and indicates it would be used at 2-5 percent of the net weight of the product, but does not estimate what the total intake would be from this consumption. Your estimate that consumption of silk protein hydrolysate from its use in dietary supplements would be 5 grams (g) daily does not address the actual subject of your submission - i.e., consumption of the ingredient in conventional foods.

Quality and quantity of information to support a conclusion that the intended use of silk protein hydrolysate is GRAS through scientific procedures

Under 21 CFR 170.30(a), "General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."

Your submission asserts that the basis for SilPRO's view that silk protein hydrolysate is GRAS includes scientific procedures. However, you have provided little or no information to support

that view. Under 21 CFR 170.30(b), "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information." In the narrative that SilPRO provides, SilPRO neither cites references to published information (in general, peer-reviewed scientific literature) about the identity, method of manufacture, and safety of silk protein hydrolysate nor describes the basis for SilPRO's conclusion that qualified experts have evaluated such generally available data and information and concluded that these data and information are adequate to establish safety. Rather, your narrative largely provides anecdotal descriptions of current consumption in Japan. This does not meet the standards described in 21 CFR 170.30(b).

Alternative view that the intended use of silk protein hydrolysate is GRAS through experience based on common use in food

Your submission also asserts that the basis for SilPRO's view that silk protein hydrolysate is GRAS includes experience based on common use in food. However, you have provided little or no information to support that view. Under 21 CFR 170.3 (f), "Common use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Further, under 21 CFR 170.30 (c)(2) "Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance." You have provided no such information or documentation in your submission. The unattributed statements in your submission (e.g., "while silk has been eaten by silk farm workers and others for over 1000 years...", or "Silk Food Protein Powder is used extensively in Japan by food manufacturers and processors....") do not serve as documentation of this use.

Conclusions

We have added a copy of your submission dated June 27, 2002, on behalf of SilPRO to the administrative file for GRN 000096.

We recommend that you review the agency's discussion, in the GRAS proposal, of the scientific, legal, and regulatory underpinnings of the GRAS notification program. In particular, we recommend that you review the agency's discussion of the differences between a food additive and a GRAS substance. As discussed in that proposal (62 FR 18940), a determination that a particular use of a substance is GRAS requires technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted by qualified experts. In contrast, authorization of a particular use of a substance as a food additive requires technical evidence of safety and review and approval by FDA. For this reason, we also recommend that you review the information on the home page of the Office of Food Additive Safety regarding the food additive petition process (Ref. 2). As a reminder, FDA's letter dated November 26, 2001, discusses some data and information that might be appropriate for inclusion in a food additive petition.

Sincerely,

Robert I. Merker, Ph.D.
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

References

1. Letter dated May 20, 2001, from Alan Rulis of FDA to Robert Averill. Available at http://www.cfsan.fda.gov/~lrd/foodadd.html.

2. A series of guidance documents are available at http://vm.cfsan.fda.gov/~lrd/foodadd.html

Enclosure: Letter dated November 26, 2001, from Andrew Laumbach of FDA to Robert Averill.
Hard copy cc: **GRN 000096, CTS 82032**
Electronic mail cc:
HFS-200 (LMTarantino) HFS-205 (GHPauli)
HFS-255 (AMattia, MDiNovi, PMGaynor, LSKahl, LSPellicore, RIMerker, TTwaroski, REdelstein)
HFS-265 (GBiddle, SVarner, ALaumbach)
Electronic reading file: FARM:\RMERKER\GRN LETTERS\83032response.wpd
Filename: 83032response.wpd
R/D:HFS-255:RIMerker:202-208-7762:8/28/02, 10/07/02, 10/22/02, 10/25/02
Edited by: HFS-255: LSKahl: 10/20/02; 10/30/02, 11/15/02
Init: HFS:255: RHarris: 10/9/02, REdelstein: 10/23/02, TTwaroski: 10/29/02, LSKahl: 10/30/02
F/T:HFS-255:RIMerker:11/22/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

November 26, 2001

Mr. Robert Averill
Director
The New Silk Road, Inc.
P.O. Box 105
Montpelier, VT 05601

Dear Mr. Averill:

This is in response to your letter of October 6, 2001, proposing the use of silk powder for use as a direct food additive in any food and beverage. We note that the intended use in food is not stated, however, we surmise that it might be intended to be a nutritive supplemental source of amino acids derived from hydrolyzed silk protein. We have examined your letter that you purport to be a food additive petition and we conclude that it has numerous deficiencies that prevent us from considering your submission as a satisfactory petition. We will discuss some of the deficiencies below.

The first of the fundamental deficiencies is in regard to the petition format. Secondly, there are deficiencies with regard to the pertinent information concerning the proposed additive. From our review, it is clear that you made little effort to follow the required format that was established to allow the review of scientific information in a reasonable and orderly fashion. Briefly, you did not attempt to outline the supportive scientific information in the format manner, but rather you simply attached what can best be described as copies of your e-mail, a product advertisement flier, an English translation of a rambling article entitled "New Applications for Silk", and other translations of commercial newspaper articles containing testimonials of no scientific merit. Moreover, throughout these attachments are undocumented medical claims (e.g., treatment of dementia, cholesterol, and alcohol intake) that strongly suggest that the intended use is a drug use. We advise that drug claims for food additives may lead to regulatory action by the agency.

From information that you provided to us, it appears that the source material for the additive is scrap silk material left over from textile manufacture. This scrap material may well contain toxic chemicals and dyes that could be harmful if ingested. You have provided no information that can assure the safety of the scrap source silk materials, although the information refers to tests performed at the Kyoto Health Testing Center. We request a copy of the test results from the test center, together with the test data that was reviewed by the testing center so that the FDA can make its own safety evaluation.

We also request chemical analysis information and validation studies on several (at least five) different batches of the scrap silk textile material that would serve as the source material.

We gather from the imprecise translation of the information that the silk is converted into amino acids and/or oligopeptides by hydrochloric acid hydrolysis carried out at 110 degrees C for 48 hours. We request a detailed description of the hydrolysis process, including an analytical analysis of the products formed based on chemical composition. We believe that described hydrolysis unusually harsh compared with typical commercial processes. If the crude description of your hydrolysis process is correct, then we can expect a detrimental effect due to amino acid racemization to the formation of toxic products by the degradation of the protein treated at elevated temperatures, and perhaps pH extremes. We note that there are publications in the food literature that report such changes (Liardian, R., and Hurrell, R.F., Amino acid reacemization in heated and alkali-treated proteins. J Agric. Food Chem. 31, 432-437, 1982). We request information on how the proposed processing conditions compare to techniques currently used in protein processing. We also ask you to discuss whether the proposed pH levels exceed pH conditions currently used in protein processing and increase possible exposure to toxic/antinutritive by-products of the procedure.

We also note that although the additive is proposed as an ingredient to be added to foods you supporting information also says that "...The characteristic odor of the hydrolyzed silk powder is not desirable in making food stuffs." The food laws of this country contain language that defines an adulterated, and thus unsuitable, food additive as a substance that imparts an objectionable odor to food. Please explain this statement regarding the possible adulteration of food by use of the additive.

The submission is also deficient from the standpoint of missing information. For example your submission refers to diagrams, yet none were provided. In you submission you claim an exclusion from an environmental impact under section H, yet no supportive statement or information was provided. We consider petition submissions to be incomplete if they lack this environmental information.

Your submission shows that you intend to use this additive (amino acids from silk protein) in "any existing" food and drink, thus without regard to food type, at levels up to 4 grams on each and every food (apparently including infant foods). Explain to us how this unlimited and unrestricted use would not lead to problems such as unbalanced amino acid intake in infant diets, and the diets of those certain individuals who would over indulge. Such unlimited exposure to certain amino acids, outside of a normal diet, may pose some peril to those, for example, with some form of kidney and liver failure. Such individuals should use arginine only while under medical supervision.

As you are now aware, there are many reasons why we consider your submission deficient, including other reasons that we believe should be discussed later in the context

of a more complete petition (e.g., labeling, computer searches for toxicological data, estimation of dietary exposure in consumers, etc.). Again we advise you that at this time your submission does not meet the criterion of a food additive petition. If you intend to prepare an improved petition, please allow us to aid in the preparation of a petition.

Sincerely,

Andrew D. Laumbach, Ph.D.
Division of Petition Review, HFS-215
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: HFA-224 HFS-200 HFS-215 HFS-225 HFS-246
Letter No. 78183
R/D:HFS-215:ADLaumbach:11/2/01
F/T:HFS-215:ADLaumbach:11/26/01

PROJECT: 78183 CFSAN EXECUTIVE CORRESPONDENCE OFFICE: OFAS
LEVEL:

DATE OF DOCUMENT: 2001/10/06 DATE RECEIVED: 2001/10/18 DATE DUE: 2001/11/08
DATE DONE: / /

FROM: ROBERT AVERILL, THE NEW SILK ROAD INC.

SUBJECT: REQUESTING TO USE SILK PROTEIN POWDER FOR USE IN FOODS DIRECTLY AS POWDER OR IN PROCESSED OR PACKAGED FOODS OR BEVERAGES

ACTION: (X) PREPARE DIRECT REPLY

SENT TO	SENT FROM	DATE SENT	ASSIGNED
HFS-215	HFS-205 PJC	10/18/2001	
		10/24/01	

INSTRUCTIONS: PLEASE RESPOND DIRECTLY

COMMENTS:

Draft – Not for Implementation

FOOD ADDITIVE PETITION SUBMISSION

Form Approval: OMB No. XXXX-XXXX
Expiration Date XXXXXXXXXXX
See Reverse for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW USE OF A FOOD ADDITIVE
(Title 21, Code of Federal Regulations, 171)

FOR FDA USE ONLY

PETITION TYPE	PETITION NUMBER	RECEIVED DATE

APPLICANT INFORMATION

1. NAME OF APPLICANT
THE NEW SILK ROAD, INC.

2. DATE OF SUBMISSION
5 OCT 2001

3. TELEPHONE NO. *(Include Area Code)*
802 229 1006

4. FACSIMILE (FAX) NO. *(Include Area Code)*
802 229 1150

5. APPLICANT ADDRESS *(Number, Street, City, Country, and ZIP Code or Mail Code)*
Number and Street: POB 105
Street Address
City and State: City MONTPELIER State Code VT
Country
Zip Code or Mail Code: Zip_Code 05601

6. AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP code, Telephone & FAX number)* **IF APPLICABLE**
Name: ROBERT AVERILL
Agent Name
Number and Street: Agent Address POB 105
City and State: City MONTPELIER ST VT Zip 05601
Zip Code or Mail Code
Telephone No. (Include area code) Phone Number 802 229 1006
Facsimile (Fax) No. (Include area code) Agent Fax Number 802-229-1150

SUBMISSION DESCRIPTION

7. PETITION TITLE
SILK PROTEIN POWDER

8. ADDITIVE FUNCTION
☒ Direct ☐ Indirect

9. PRODUCT
SILK PROTEIN POWDER

10. TECHNICAL EFFECT

11. CHEMICAL IDENTITIES

CHEMICAL TYPE*	CAS NUMBER	CHEMICAL NAME	TRADE NAME (IF ANY)	STRUCTURE
P	000000000			
			000080	

* P – Primary chemical, C – Constituents (including residual monomers, residual solvents, impurities, by-products, catalysts, and etc.)

78183

The New Silk Road, Inc.
POBox 105
Montpelier, VT 05601
6 October 2001

Silk Protein Powder. For use in foods...directly as powder or in processed or packaged foods or beverages.

Petitions Control Branch
Food and Drug Administration
Department of Health and Human Services
Washington, DC 20204

Dear Sirs:

The undersigned, Robert Averill submits this proposal pursuant to section 409(b)(1) of the Federal Food, Drug and Cosmetic Act with respect to

Silk Protein Powder as an additive to foods and beverages

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including composition of the food additive, its physical and biological properties, and specifications prescribing the minimum content of the desired components and identifying and limiting the reaction byproducts and other impurities (please see attrachment A).

1) product is produced by hydrolysis and dried to powder form. It contains nothing but the natural form of silk protein extracted from the cocoon by using the cocoon, at near end of thread unwinding process to hydrolyze and then to powder.

B. The amount to be used by a food manufacturer will be from 1% to 5% of the net weight of the manufacturer's food or beverage

product....the amount to be determined by the manufacturer.

1) the consumer at home who chooses to use the powder itself will use an amount equal to 1/4 teaspoon daily or 2 to 4 grams daily.....directly "straight" as the powder itself or in a beverage or sprinkled on a food.

2) labeling will be provided by the manufacturer of the food product to which the silk protein powder is added. The distributor, The New Silk Road, Inc., will label the 250 gram sealed aluminum bags of silk protein powder for manufacturer or direct consumer use as follows:

calories	400/100g
protein	96.9%
sodium	280mg/100g
water	2.6%
fat	0
cholesterol	0
gluten	0
lactose	0
casein	0
sugar	0
carbohydrates	0

nutrition labels will be determined and printed for The New Silk Road, Inc. by Nebraska Biological Services.

3) tolerance level is extremely high and not determined.

4) Silk protein powder will have no effect on any food or beverage on which or in which it is used.

D. The food additive silk protein powder is added to the food and is not an ingredient of any existing food or beverage.

E. Tests: please see reports attached.

F. Tolerances proposed.....not determined. Believed to be extremely high. (some rare individuals have an intolerance to silk itself).

G. no modification of any existing regulation is desired.

H. The petitioner claims exclusion from 21 CFR 171.25.30 and 25.32.

Yours very truly
The New Silk Road, Inc.
by Robert Averill Director

800-722-1419
802-229-1150 fax
info@newsilk.com email

newsilkRAverill

From: "Lyle Fox" <lbfox@gol.com>
To: "newsilkRAverill"
Sent: Thursday, May 24, 2001 2:25 AM
Subject: Re: silk candy

Dear Mr. Averill,

Thank you for your e-mail and fax, both duly received. I'm glad you liked the toothpaste idea---I've got lots more.

Today I will be sending you the English-language material. In the meantime, I hope the following is helpful.

AMINO ACID BREAKDOWN

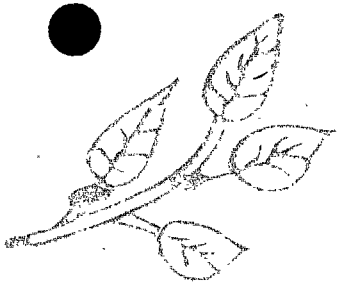
Arginine	0.04%
Lysine	0.05%
Histidine	0.09%
Phenylalanine	0.18%
Tyrosine	0.68%
Leucine	0.14%
Isoleucine	0.16%
Methionine	too small to detect
Valine	0.96%
Alanine	36.8%
Glycine	46.0%
Proline	0.12%
Glutamic Acid	0.75%
Serine	10.5%
Threonine	0.44%
Aspartic Acid	1.16%
Trytophan	too small to detect
Cystine	0.02%

This analysis was conducted by the Japan Food Research Laboratories, a government-licensed lab.

SILK CANDY INGREDIENTS
Malt, white sugar, yogurt powder, yogurt flavoring, silk powder (3%)

Note: Yes, in answer to your question, the product does contain sugar BUT it can be made without sugar if this is better for you. In fact, the current yogurt flavor can be substituted for any flavor you prefer (ie, orange, blueberry, etc). The smoothness of the silk with the yogurt seems to make a nice milky match, but this is simply a matter of local preference. Also, since xylitol is so popular now in the US and Japan as a "healthy" sugar substitute with anti-bacterial properties, we could also use this instead of sugar. The cost might rise, however, since xylitol is not cheap and chewing gums in Japan with xylitol are more expensive than regular gum or regular sugarless gum.

SILK CANDY ANALYSIS (per 100 grams)



ATTACHMENT A

MANUFACTURERS' SAMPLE OFFER

This is an opportunity to put one or more of *your* products in a unique health / fitness category.

A 250 gram(approx 1/2 lb.), sealed aluminum pouch of silk protein powder is available for experimental use.

Please fax or post your request with the name of your company and postal or UPS address.

800-722-1419
fax 802-229-1150
email: info@newsilk.com

000085

Qualities of Silk Protein Powder

FIBROIN reduces blood cholesterol levels. Research shows blood cholesterol levels rise rapidly after ingestion of casein protein in food. Replacing only 5% of the casein with silk protein suppresses the rise in cholesterol.

Silk Protein Powder has 18 Amino Acids and extremely high levels of the 4 most important aminos:

GLYCINE - helps trigger the release of oxygen for the body's cell-making processes, is a blood cholesterol control, and promotes the metabolism of alcohol thus assisting liver function;

SERINE - is a source of glucose storage in the liver and muscles, and helps to strengthen the immune system;

ALANINE - is an important source of energy for muscle tissue, the brain and the central nervous system, and helps in the metabolism of sugars and organic acids.

ASPARTIC ACID - aids in the expusion of harmful and toxic ammonia from the body. It may also increase resistance to fatigue and increase endurance.

Other Amino Acids present in Silk Protein Powder in moderate quantities are:

TYROSINE - which transmits nerve impulses to the brain and helps to overcome depression, improves memory, and increases mental alertness.

THREONINE - is an important part of collagen - a composition of our body tissues, cartilage and bone - which also helps prevent fat build-up in the liver.

FOOD GRADE SILK POWDER
CHARACTERISTICS: WHITE POWDER, WATER SOLUBLE, ODOR-FREE, SLIGHTLY SWEET TASTE
PH: 4.0-6.0 **WATER:** 2.64% **PROTEIN:** 96.49%
RESIDUALS: 0.87% **FAT:** 0 **ASH:** 0.5%
NITROGEN: 15.8% **SODIUM:** 280 mg/100 gms
ARSENIC: 0.9 ppm **LEAD:** 0.08 ppm
MERCURY: 0 **GENERAL BACILLUS:** 5.9×10^2
MOLECULAR WEIGHT: LESS THAN 300
CALORIES: 400/100 gms **STORAGE:** DUE TO HYGROSCOPIC NATURE, USE PROMPTLY AFTER OPENING. STORE AWAY FROM HIGH HUMIDITY.

P.E.R. (PROTEIN EFFICIENCY RATING): 95
BIOLOGICAL VALUE: 96

AMINO ACID	SIDE CHAIN	SILK SERICINE	SILK FIBROIN
GLYCINE	H	147	445
ALANINE	CH3	43	293
LEUCINE	(CH3) 2CHCH2	14	5
ISOLEUCINE	CH3CH2CH (CH3)	7	7
VALINE	(CH3) 2CH	36	22
PHENYLALANINE	C6H5CH2	3	6
SERINE	CH2OH	373	121
THREONINE	CH3CH(OH)	87	9
ASPARGINIC ACID	HOOCCH2	148	13
GLUTAMIC ACID	HOOCCH2CH2	34	10
ALGININE	NH2C (NH) NH (CH2)3	36	5
CYSTINE	(1/2) (-SCH2) 3	5	2
METHIONINE	CH3SCH2CH2	-	1
LYSINE	NH2 (CH2) 4	24	3
PROLINE	(CH2) 3CHNHCOOH	7	3
HYSTIDINE	N(CH) 2NHCCH2	12	2
TRYPTOPHANE	C6H6NHCH2	-	2
TYROSINE	HOC6H4CH2	26	52
AMMONIA,ETC.		86	-

"New Applications for Silk"

By Kiyoshi Kobayashi, Shinshu University Department of Textile Science

1. Introduction

Looking at the transition of Japan's silk industry over the years, the key indicators -- cocoon and raw silk production volumes - show a steady, precipitous drop-off. The main reason for this is the declining popularity of traditional Japanese clothing that has accompanied Westernization. This has been exacerbated in recent years by the advent of new synthetics fibers that compete with silk. Uniforms for female workers in Japanese restaurant establishments have traditionally been made of silk, but that has recently been giving way to the new synthetics. Why spend hundreds of thousands of yen on pure silk when one can have something that is impossible for the untrained eye to distinguish from silk, is far cheaper, more durable, and machine washable?

However, the downturn in the silk market is nothing new. For many decades persons in the industry have worked night and day to find ways of halting the shrinkage of the marketplace. I too have spent a lot of time and energy trying to come up with new applications for silk. If there's no demand for it in clothing, well perhaps it can prove critical somewhere else.

Accordingly, I became interested in the microstructure of silk and pursued research in this area. The starting point for research in this area is liquid silk inside the silk gland. It is possible to take it directly from the silkworm, but after use of a neutral salt to dissolve the silk and dialysis, the resulting fibroin (i.e., the major protein component of silk) fluid is the same thing.

I left this liquid fibroin sitting around and noticed that it congealed. At first I didn't pay any attention to this, but then it occurred to me that if silk could be eaten then silk might be consumed in large quantities. So, I tried some. It was colorless, tasteless and odorless. So then I added in some flavorings and found that the result was quite similar to commercially marketed gelatins. The texture was pleasurable. This marked the beginning of silk's commercialization as a foodstuff.

2. Silk's Food Properties

The animal proteins that we eat are broken down by enzymes and microorganisms in the digestive tract and the resulting amino acids and oligopeptides are absorbed through the small intestine. No matter how strong one's teeth and no matter how much one chewed, unmodified silk is not something that one can chew and eat; however, if it is made into a gelatin as described above it is quite easy to eat.

First I decided to determine the percentage of silk digestion by feeding it to rats with their food, and then measuring the nitrogen content of their excreta. The results are as shown in Table 1. In order of digestibility, silk powder is lowest, silk liquid is next, and regular food is best. I also investigated hydrolyzed silk; this has a digestion rate of 90% or higher. Silk

DATA ?

digestion and absorption can be increased by converting it into amino acids and/or oligopeptides.

Table. 1 Silk fibroin digestion rate (%)

	Rat A	Rat B	Rat C	Rat D	Average
Regular food	86.0	86.1	84.4	86.3	85.7
Silk liquid	46.8	67.5	34.2	41.1	47.4
Silk powder	29.3	28.0	28.5	24.4	27.6

So, how can silk be converted into amino acids and/or oligopeptides? The process is acid hydrolysis [?], which has been know for a long time.

If one part of silk is put into a flask with 100 parts of dilute [translator's note: Japanese uses a more specific term; it's some kind of a standard but I don't know the precise dilution] hydrochloric acid, and hydrolysis is carried out at 110 degrees C for 48 hours, the silk becomes amino acids and/or oligopeptides. To this is added the same amount of sodium hydroxide for neutralization. The resulting sodium chloride (table salt) is removed and the remainder concentrated and freeze dried. The result is pale yellow silk powder. It has a mild sweetness.

Table 2. shows (in mol %) some of the more than 10 amino acids in silk, including glycine (45%), alanine (30%), serine (11%), tyrosine (6%), and others (several %). Approximately 6% of the total are essential amino acids. Silk has a definite nutritional value as a foodstuff.

Table 2. Silk's amino acid composition (residual base parts/1000)

Amino acid	Side chain	Domestic silkworm sericine	Domestic silkworm fibroin
Glycine	H	147	445
Alanine	CH3	43	293
Leucine	(CH3)2CHCH2	14	5
Isoleucine	CH3CH2CH(CH3)	7	7
Valine	(CH3)2CH	36	22
Phenylalanine	C6H5CH2	3	6
Serine	CH2OH	373	121
Threonine	CH3CH(OH)	87	9
Asparginic acid	HOOCCH2	148	13
Glutamic acid	HOOCCH2CH2	34	10
Alginine	NH2C(NH)NH(CH2)3	36	5
Cystine (1/2)	(-SCH2)3	5	2
Methionine	CH3SCH2CH2	-	1
Lysine	NH2(CH2)4	24	3
Proline	(CH2)3CHNHCOOH	7	3
Hystidine	N(CH)2NHCCH2	12	2
Tryptophane	C6H6NHCH2	-	2
Tyrosine	HOC6H4CH2	26	52
Ammonia, etc.		86	-

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According to previous amino acid research, glycine and serine help to reduce cholesterol levels in the blood, alanine assists the metabolization of alcohol, tyrosine is reported to be

indispensable for treatment of dementia. Accordingly, it is expected that silk hydrolysates will prove helpful in preventing geriatric diseases, which are expected to be a growing problem as the population ages.

Animal experiments were performed to confirm these functional charactistics of silk.

First an experiment on alcohol metabolism was performed. Table 3. shows measurements of blood ethanol levels in rats. Rats that were given silk hydrolysates prior to administration of ethanol have lower levels than rats that were not given them, indicating that these compounds assist the metabolization of alcohol. Alanine becomes a source of energy to stimulate the cycle whereby acetaldehydes and NADH produced by the metabolization of alcohol are broken down. Silk is effective against the administration of large doses of ethanol because it is about 30% alanine.

Table 3. Rat blood alcohol concentration according to type of fibroin given

Specimen	Blood alcohol concentration (mg/ml)
Nothing given	3.21 +/-0.21
Basic specimen	2.78 +/-0.22
Basic specimen + fibroin (1N HCl 30 min)	2.44 +/-0.21
Basic specimen + fibroin (1N HCl 48 hr)	2.14 +/-0.38

Also, glycine, which comprises the majority portion of silk amino acids, tends to reduce blood cholesterol levels.

Diagram 1. shows the influence of fibroin on blood cholesterol levels. When the protein in food is casein, rats' blood cholesterol concentrations rise rapidly immediately after ingestions. In contrast, replacing 5% of the casein in the food with fibroin suppresses the rise in blood cholesterol significantly.

Glycine's tendency to lower blood cholesterol levels can be expected to tie into prevention of high blood pressure and cerebral strokes.

Also, the 6% tyrosine component of silk becomes a dopa through the action of tyrosine hydroxilase; this is essential for sufferers of Parkinson's disease.

2 Diagram 1. Change in blood cholesterol levels of high-cholesterol rats given fibroin
Vertical axis: blood cholesterol concentration mg/dl; horizontal axis: duration of feeding, days
Squares: Casein
Triangles: Fibroin after 3N HCl hydrolization for 48 hours

3. Commercialization of silk foodstuffs

Kyoto's Tango District is one of Japan's major areas for manufacture of silk textiles, consuming about one-third of the raw silk used in Japan. The main use is in producing silk crepe. Back when kimono were still popular in Japan, nobody cared about silk

scrap - they would burn three tons of it each month without giving it much thought. But with the decline in sales, profits have been squeezed thin and now people in the industry are keen on finding ways to use even this silk scrap profitably. Having been processed into fabric once, this cannot be used as a raw material for the textile industry. (To avoid damaging machinery, the thread would all have to be unwound, which is practically impossible.) The first use considered for this scrap material was filling in futon. The scrap fabric is cut up into small pieces and made into a cottony consistency. This proved difficult since silk is "slippery," unlike cotton or wool fibers which cling together more readily. This turned out to be a dead end.

However, Mssrs. Tsuyoshi Isehata, Industry Section Chief of Kaya Town Hall, and Shuji Taniguchi, a textile manufacturer, saw my article in "Sokai" magazine about making silk into food, and they proposed that I do research using the scrap silk from crepe manufacture.

I and other researchers were interested in an inexpensive source of silk for doing research, so we had an immediate harmony of interests, and it was decided to commence research into commercialization of silk foodstuffs. That was in June, 1990.

It was in early 1991 that silk powder made through hydrolysis first went to market. Tests performed at the Kyoto Health Testing Center showed the product to be devoid of any harmful effects. The sweetness of silk powder was due to the presence of glycine, alanine, and serine, and the light yellow color could be removed by passing through activated carbon.

The town has been able to produce many foodstuffs, including candies, rice gruel, rice crackers, jellies, udon, soba, and cakes, centering around the functionality of silk. All have been well received.

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4. Silk Oligopeptides

The characteristic odor of hydrolyzed silk powder is not desirable in making foodstuffs. Accordingly, in order to improve this, enzymes were used to produce oligopeptides. Oligopeptides are both odorless and colorless. Oligopeptides up to about 5 units in size are readily absorbed through the intestinal wall. After deliberating various enzymes, it was determined that the protein breakdown enzyme actinase (obtainable from the filtration fluid of the actinomyses "Streptomyces griseus" culture) is appropriate. This enzyme breaks down fish and meat protein from 200 to 300. Even better is the fact that given time, it self-destructs and therefore it is not necessary to remove it.

First, an amount of the enzyme equivalent to 10% of the silk (by weight) is put in a 2% solution of the silk. At 37 degrees C the processing time was changed and hydrolysis carried out. After breaking down, the solution is rapidly boiled to inactivate the enzyme. The result of this decomposition product's gel filtration is shown in Diagram 2. From the right hand side there are peaks A, B, C, and D. "A" represents the molecular weight around 100, "B" around 200, "C" around 400, and "D" around 600. As hydrolization

time is increased, "D" is absorbed into "C." Next amino acid analysis was conducted to investigate the peptides in each peak. Peak "A" is 60% tyrosine, glycine and analine are 10-20%, and the other silk amino acids are also present in small quanitities.

Diagram 2. Gel filtration of enzyme (actinase) decomposition compounds
Vertical axis: Light absorbtion in 210mm; Horizontal axis, Water flow volume (ml)

Peak "B" represents di- or tri-peptides and through N terminal analysis becomes Gly-Ala-Gly or Ala-Gly. Since the peak is rather small, the amount present is small.

When the enzyme processing time becomes long, peak "D" shifts in the lower molecular direction ("C"). Peak "C" is the largest (cf. Diagram 3). The mol ratio is about 3:2:1; as a result of deliberating the amino acid alignment it became Gly-Ala-Gly-Ala-Gly-Ser. These peptides also tend to reduce blood cholesterol levels.

Diagram 3. Peak "C" amino acid analysis
Vertical axis: composition ratio (mol %)

5. Silk As a Biological Material

Applications research into silk's functions beyond the realm of foodstuffs are also being carried out (Diagram 4.) Silk powder's applications are influenced by molecular weight. As explained above, amino acids and oligopeptides are suitable for use in foods.

Diagram 4. <Far left> Silk; (Second from left) Fibers / Powders / Solutions
<Third from left> Silk thread gland / Cocoons / Raw silk / Silk thread
[Acid hydrolysis] Amino acids/oligopeptides
Molecular weight 100-500
[Acid or base degredation] Medium molecular weight powders
Molecular weight around 10,000
[Jellification/agitation] High molecular weight powders
Molecular weight 10,000 or higher
[Enzyme breakdown] Low molecular weight powders
Molecular weight 1,000 or less
Films/Layered sheets
Molecular weight 60,000 or higher
Reprocessed raw silk thread
<Far right>
Silkworm gut
Dolls/freshness preservatives
Sewing thread/musical instrument strings/tennis racket gut
Interior furnishings/bed sheets/towels
Foodstuffs/Bath salts

Cosmetics/signature seal material (inzai)/"tortoise shell"/biodegradable plastics
Cosmetics
Foodstuffs/cosmetics
Accessories ("tortoise shell")/coated fibers
Artificial skin/contact lenses

The simplest way to produce powder is to use an acid or base to degrade process the silk fibers, and then to wash, dry and pulverize them. There are also ways of making powder from silk solution. The solution can be gelled and freeze-dried; the result is a powder of high molecular weight. The lower the concentration of the solution, the finer the powder that can be achieved, with the major component 10 microns or less. If the silk solution is agitated, the silk precipitates out in a fiber configuration. If this is then dried and pulverized, a powder is obtained. Low molecular weight powders are made through enzyme hydrolysis. The type of enzyme(s) and additives, the processing time and other factors produce variations in molecular weight.

High molecular weight powders are already used commercially in cosmetics. Silk absorbs ultraviolet radiation is made from moisture-preserving amino acids, so it has the potential for use in cosmetics. It is effective in cosmetics when 5-10% high molecular weight silk is added (Diagram 5). Recently, silk amino acids and oligopeptides have been found to provide nutrients to the skin (collagen) and to stimulate collagenase.

Diagram 5. Different powders added to cold creams and their effects on sunlight
Vertical axis: degree of yellowing; horizontal axis: Silk, Wool, Chitin, Chitosan, Commercially marketed product
Powders were added in a ratio of 5% to the commercially marketed product, applied to silk fabric and left exposed to sunlight for one week, and then the degree of yellowing was measured.

Low molecular weight powders (thousands) have been found effective in hair treatments, and thus are added to shampoos, rinses, lotions, etc. Also, amino acids and oligopeptides are added to commercial bath salts.

Medium molecular weight powders are used in plastics. Degraded powders are appropriate for these applications. When silk is degraded with an acid or base, the noncrystalline region is washed out and the crystalline region remains. Processing with dilute acid for one hour at 100 degrees C produces an 80% yield of silk powder. If powder with water content of around 10% is placed in a mold under pressure of 1,000 kg/cm2 at a temperature of 120 degrees C, a yellowish silk plastic is formed. If placed in water it absorbs water and develops cracks, but if an appropriate resin is added this tendency disappears. This is used for making signature seal material (inzai) and accessories.

Silk film is made by flowing silk solution over a hydrophobic synthetic sheet such as polyethylene and then drying. The

thickness of the film can be controlled by varying the concentration of the solution. It is colorless and transparent. If several tens of these sheets are piled up and heat and pressure applied, a yellowish transparent sheet is created; through the addition of coloring agents an artificial tortoise shell can be made.

Films made from cast solution have random molecular weights; these dissolve in water but can be made nonsoluble in water through the use of alcohol or other polar solvent processing. Ductility is not very good, but through the addition of a plasticizer a flexible film can be obtained.

If silk film is applied to a wound opening, since silk is well received by the body, allergic reactions do not occur. Also, it is possible to create films that dissolve through contact with bodily fluids. Such films are also highly permeable to oxygen, so research is now being done on how to make silk contact lenses.

6. Conclusion

Non-textile applications of silk as a rule use only silk which is not suitable for textile applications. Even though silk (raw silk) is much cheaper than in the past, it still costs about 7,000 yen per kilogram. Raw silk should continue to be used for textiles. Silk undergarments promote the metabolism of the skin and are good at absorbing and wicking away moisture, so silk makes for healthy clothing. As the body moves, the silk microstructure acts as brush, cleaning the skin of microorganisms and debris. In other words, silk is naturally antibacterial. Silk cosmetics provide nutrients to the ~~skin (collagen) and~~ cut out ultraviolet radiation. Silk bath ~~salts provide the skin with amino acids~~ and thus ~~inhibi~~t aging of the skin. Silk shampoos give the hair a protective coating ("treatment"). Finally, silk foodstuffs prevent geriatric diseases. Truly, silk is one of our best friends for good health.

"Asahi Shimbun" Newspaper Article
July 12, 1998

<HEADLINES>
The World of Silk Broadens
Powder used in foods; also silk underwear and cosmetics
Diverse applications emerging through new processing technology
The sweetness of amino acids yet good for dieting
<CAPTION AT LEFT OF PHOTO>
Silk foodstuffs, shampoos, cosmetics and other goods at the Japan Silk Center, Yurakucho, Tokyo
<BODY>
The traditional world of silk is being steadily transformed through new processing technologies. Noodles, tofu, confectioneries and other foods containing liquefied and powdered silk components are popular for their pleasing textures. The high percentage composition of amino acids good for the skin is leading to cosmetics applications. Fibers surface-coated with silk compounds can be used in hypoallergenic underwear and bathing suits suitable for sufferers of atopic dermatitis and other hypersensitive skin ailments. For these reasons silk is the focus of increasing attention. The Japan Silk Association says that the development of new technologies is leading to a reappraisal of silk's health-related applications.

At the Japan Silk Center in Yurakucho, Tokyo, along with silk clothing, various foodstuffs and cosmetics that (at first glance) seem to have nothing to do with silk are being displayed and sold. Udon and soba noodles, candies, cookies and jellies are included.

These foodstuffs contain "silk powder," which is made from the powdered protein component of the silk fiber known as fibroein. Fibroein contains 18 amino acids. The Center's Koji Mitsui says, "Research in recent years shows amino acids like these to be effective in assisting liver function and in reducing blood cholesterol and blood sugar levels."

Because silk powder gives foods a silky texture and resilience, "The number of food companies adding silk powder to their soba and udon noodles is growing rapidly. Each company has their own ratio for adding in the powder."

Kikuya Kobo, a confectionery manufacturing and sales company based in Koriyama, Fukushima Prefecture, has started to sell pound cakes, donuts and other baked goods containing silk powder mixed with lees of bean curd. Since the amino acids are sweet the company is able to reduce the sugar content by 20-30% -- a boon to dieters.

The powder is made from fragments of silk thread and unusable silk thread.

Kaya-cho, Kyoto (which is where Bingo chirimen noodles are made) has established a third sector company to produce silk

"NIKKEI RYUTSU SHIMBUM" NEWSPAPER ARTICLE
MAY 16, 1998

<HEADLINES>
-- Trends Now --
Silk is Healthy
Good to wear, good to eat
Noodles: resilient texture, candies: delightful sheen
<CAPTION>
Udon noodles with silk powder have a resilient texture
<INTRODUCTION>
Silk, traditionally something you wear, is now becoming something to eat. Foodstuffs containing compounds from natural fiber silk are gaining in popularity. Because silk contains compounds that aid liver function and lower blood cholesterol levels, it is gaining fans among health-conscious consumers. Sensing the making of a boom, some hotels and restaurants are adding foodstuffs containing silk to their menus. (Hideki Shindo)
<BODY>
"You know, you can eat silk." Yuko Tsuda, manager of an order-made silk clothing shop in Tokyo's Kita Aoyama, has a professional love for items made from silk, but she also frequently eats udon noodles and candies containing silk compounds. "The noodles have a resilient texture and the candies a delightful sheen - very much in keeping with the mental image I have of silk."

Mrs. Y (58), a housewife in Nerima, Tokyo, is fond of eating somen noodles containing silk. "They not only taste delicious when freshly prepared, they are also fine after some time has passed."

Besides somen and udon noodles and candies, the growing list of popular silk-containing products includes tofu and ice cream.

Mr. Aoyanagi, head of the sales section in Silver Artre (based in Tonosho-cho, Kagawa Prefecture), which sells silk-containing udon, explains, "The silk compounds give the noodles a firmer, more resilient texture. They don't get soft even after some time has passed, which makes them ideal for use in pot dishes."

Silver Artre commenced sales from 1990. In the beginning many people were leery because of the association with silk cocoons. "Sales began taking off significantly about three years ago. In 1997 we sold 80,000 bags, twice our sales of the previous year," reports Aoyanagi.

Last autumn saw the introduction of silk in some of Akita Prefecture's renowned Inaniwa udon. According to Kanbungonendo (based in Inakawa-cho, Akita), maker of "Inaniwa no Kinu-iri Tenai Udon," despite selling for \3,000 for six 100-gram bundles (70% more than regular Inaniwa udon), last year they sold 20,000 100-gram servings. President Kunzo Sato is confident they will sell 40,000 servings this year.

Sakatoshi Seimensho (based in Yoshino-son, Nara Prefecture), commenced sales of "Silk Somen" from last summer. Like udon, the firm, resilient texture, is what makes it stand out. As an

indication of their popularity, at a taste test of more than 20 different somen noodles last spring, according to director Yoshiko Sakaguchi, "plates with noodles containing silk were emptied before any of the others."

Actively promoting sales of these silk-containing foods is the National Federation of Silk Agriculture Associations [?] (Zen'yoren). In 1997, sales volume of silk-containing foods reached \60 million. Although that monetary amount is still small, "It is expected that 1998 sales volume will reach 150% of that amount" (Silk Department Director Watanabe).

The burgeoning popularity of silk-containing foods is because of the increasing interest in silk as a health food.

Silk fiber proteins contain 18 amino acids, including alanine and aspartic acid. In particular, the percentage composition of glycine is eight times that of cow's milk, and six times that of chicken eggs. These compounds assist liver function and promote the metabolization of alcohol, and reduce levels of cholesterol and sugar in the blood. The silk fibers are diffracted and the compounds extracted and the resulting liquids or powders are added to the foods.

Some people are taking the powder. One man, age 74, reports that he started to take silk powder for his high blood pressure, and that it is easy to drink if mixed with milk or other beverage.

<HEADLINE>
Popular at the breakfast table; also used in tofu and ice cream
Appearing in hotels and restaurants

<CAPTION>
Various foods containing silk
<BODY>
More and more hotels and restaurants are beginning to sell foods containing silk.

The Kinugawa Plaza Hotel, at the Kinugawa Hot Springs in Tochigi Prefecture, started offering a breakfast set featuring silk-containing udon in October of 1997. They make the noodles themselves and serve them as a hot pot dish. Director Michi Aoki says, "They were popular with our guests, who sometimes come to breakfast with a hangover or suffering from lack of sleep, so we decided to make these noodles a permanent part of the menu."

"Restaurant Mayu," in Nasu-cho, Tochigi, has been serving silk-containing udon since 1994. At a restaurant in a rental cottage called "Mayu no Sato" (due to the many mulberry fields nearby), they included this on the menu in 1994. Nippon Leisure Kaihatsu (based in Nishi Nasuno-cho, Tochigi), the company managing the rental cottage, imports the raw ingredients from China and manufactures and sells silk powder.

Next spring, the gift shop next to the restaurant will be converted into a shop specializing in silk-related products, called "Mayu no Yakata." Beginning with silk-containing foods, silk-containing cosmetics, shampoos, bath salts, silk accessories and craft items using cocoons will be sold in the shop.

"Kinu no Sato," a restaurant in Fukushima City, specializes in tofu containing silk, served cold (yakko) and in salads. Mari

"SOKAI MAGAZINE" ARTICLE

<HEADLINES>
Growing numbers of people are discovering that eating "silk" can improve type C hepatitis, fatty liver, atopic dermatitis.
Yoshifumi Hayashi, age 42. Company employee. Wakayama Prefecture
"Regular Consumption of Silk Normalized My Diabetes and Fatty Liver Test Values and Reduced My Blood Pressure and Weight - I'm Thrilled!"
<SUBHEADING>
My father also had diabetes, so I was on the lookout
<BODY>
I work for a construction company where they give all employees a physical examination every April. Until last year, nothing came up as particularly bad, and I was confident in my physical strength. Accordingly I participated in all the usual events during the year without any concern.

However, last year I was a bit worried when I went for the physical exam. For a few months I had been feeling a vague listlessness and I had been finding it hard to shake off a lingering cold. I knew I was not in the best physical condition; in fact I was a little worried about what the physical exam might turn up.

It turned out my worries were well founded. I was diagnosed as having a suspicion of being in the early stages of diabetes and fatty liver, since my blood sugar and fat levels were high. My blood sugar level on an empty stomach at that time was 120mg (the normal range is 60-110mg), and fat was 180mg (the normal range is 60-150).

My father was also diabetic so I thought that I too needed to be on the lookout for it. However, frankly speaking, I thought that worries about such geriatric diseases were far ahead of me.

Regarding fat as well, I am on the heavy side at 95 kilograms, but because my height is 178 centimeters, I didn't think of myself as all that overweight. I do consume alcohol, but in moderation. I enjoy meat and fish, but also consume lots of vegetables, and endeavor to eat a wide variety of foods.

Just when I was wondering where I should go for treatment, a friend an acquaintance employed by as a nurse Dr. Osami Kajimoto (cf. pages 182-183) introduced me to that hospital.

I was immediately examined and based on that, was encouraged to take silk powder, which is effective in removing fat and in lowering blood sugar.
<SUBHEADING>
I lost 5 kilos without changing my diet
<BODY>

I am worried about side effects of medicines and thus do not like them. However, as this product is not a medicine I decided to give it a try. I was told to dissolve some in water and drink it each evening before dinner.

I expected that both diabetes and fatty liver, if still in the early stages, would respond quickly, so I took the silk powder every day as instructed. Four months later, when I went for my next examination, my blood sugar and fat levels were 110mg and 150mg respectively - both lower than in the spring.

Even though I hadn't been following any particular regimen of exercise or changing my diet, I had lost four or five kilograms - what a surprise! Also, my blood pressure, which for several years had been hovering around 135mm, was down to 125mm.

Since then I have been getting examined once every two months. My blood sugar level is always within the normal range and my fat level has fallen even further, to 110mg, and I have been told that there is no longer any worry concerning this. Accordingly, I no longer feel listless and am free from colds. I feel great - as if I'm back in my early 30s.

I think that one factor in my good health is the regularity of my bowel movements. Previously I frequently went back and forth between constipation and diarrhea, but now I pass one very good stool each day.

My weight is currently around 90 kilograms. I am originally on the muscular side and don't feel a tremendous change in my condition as a result of losing five kilograms, but my trousers fit a little more loosely now.

What really pleases me is that I have been able to overcome these geriatric diseases without the use of synthetic chemicals, but rather through the use of a natural health food. I am very relieved and very grateful to Dr. Kajimoto for introducing this to me.

<SUBHEADING>

Yoshitake Tanaka, M.D., Shirausagi-kai Shirai Hospital

Silk peptides brought down blood pressure

In Mr. Hayashi's case, since he originally tended toward high fat and overweight, normally he would require treatment through diet and exercise. However, these lifestyle changes are hard for may people to implement even under a physician's supervision.

Mr. Hayashi clearly shows signs of reduced fat and weight since taking silk protein enzyme derivatives. I think that the net effect of this is the same as if he had implemented a regimen of diet therapy, thus improving the abnormal blood sugar levels seen on an empty stomach, which are characteristic of the early stages of diabetes.

Also, among the peptides in the silk protein enzyme derivatives are some that lower blood pressure. The reduction of body weight and this action of the peptides probably worked in concert to reduce blood pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

November 26, 2001

Mr. Robert Averill
Director
The New Silk Road, Inc.
P.O. Box 105
Montpelier, VT 05601

Dear Mr. Averill:

This is in response to your letter of October 6, 2001, proposing the use of silk powder for use as a direct food additive in any food and beverage. We note that the intended use in food is not stated, however, we surmise that it might be intended to be a nutritive supplemental source of amino acids derived from hydrolyzed silk protein. We have examined your letter that you purport to be a food additive petition and we conclude that it has numerous deficiencies that prevent us from considering your submission as a satisfactory petition. We will discuss some of the deficiencies below.

The first of the fundamental deficiencies is in regard to the petition format. Secondly, there are deficiencies with regard to the pertinent information concerning the proposed additive. From our review, it is clear that you made little effort to follow the required format that was established to allow the review of scientific information in a reasonable and orderly fashion. Briefly, you did not attempt to outline the supportive scientific information in the format manner, but rather you simply attached what can best be described as copies of your e-mail, a product advertisement flier, an English translation of a rambling article entitled "New Applications for Silk", and other translations of commercial newspaper articles containing testimonials of no scientific merit. Moreover, throughout these attachments are undocumented medical claims (e.g., treatment of dementia, cholesterol, and alcohol intake) that strongly suggest that the intended use is a drug use. We advise that drug claims for food additives may lead to regulatory action by the agency.

From information that you provided to us, it appears that the source material for the additive is scrap silk material left over from textile manufacture. This scrap material may well contain toxic chemicals and dyes that could be harmful if ingested. You have provided no information that can assure the safety of the scrap source silk materials, although the information refers to tests performed at the Kyoto Health Testing Center. We request a copy of the test results from the test center, together with the test data that was reviewed by the testing center so that the FDA can make its own safety evaluation.

We also request chemical analysis information and validation studies on several (at least five) different batches of the scrap silk textile material that would serve as the source material.

We gather from the imprecise translation of the information that the silk is converted into amino acids and/or oligopeptides by hydrochloric acid hydrolysis carried out at 110 degrees C for 48 hours. We request a detailed description of the hydrolysis process, including an analytical analysis of the products formed based on chemical composition. We believe that described hydrolysis unusually harsh compared with typical commercial processes. If the crude description of your hydrolysis process is correct, then we can expect a detrimental effect due to amino acid racemization to the formation of toxic products by the degradation of the protein treated at elevated temperatures, and perhaps pH extremes. We note that there are publications in the food literature that report such changes (Liardian, R., and Hurrell, R.F., Amino acid reacemization in heated and alkali-treated proteins. J Agric. Food Chem. 31, 432-437, 1982). We request information on how the proposed processing conditions compare to techniques currently used in protein processing. We also ask you to discuss whether the proposed pH levels exceed pH conditions currently used in protein processing and increase possible exposure to toxic/antinutritive by-products of the procedure.

We also note that although the additive is proposed as an ingredient to be added to foods you supporting information also says that "...The characteristic odor of the hydrolyzed silk powder is not desirable in making food stuffs." The food laws of this country contain language that defines an adulterated, and thus unsuitable, food additive as a substance that imparts an objectionable odor to food. Please explain this statement regarding the possible adulteration of food by use of the additive.

The submission is also deficient from the standpoint of missing information. For example your submission refers to diagrams, yet none were provided. In you submission you claim an exclusion from an environmental impact under section H, yet no supportive statement or information was provided. We consider petition submissions to be incomplete if they lack this environmental information.

Your submission shows that you intend to use this additive (amino acids from silk protein) in "any existing" food and drink, thus without regard to food type, at levels up to 4 grams on each and every food (apparently including infant foods). Explain to us how this unlimited and unrestricted use would not lead to problems such as unbalanced amino acid intake in infant diets, and the diets of those certain individuals who would over indulge. Such unlimited exposure to certain amino acids, outside of a normal diet, may pose some peril to those, for example, with some form of kidney and liver failure. Such individuals should use arginine only while under medical supervision.

As you are now aware, there are many reasons why we consider your submission deficient, including other reasons that we believe should be discussed later in the context

of a more complete petition (e.g., labeling, computer searches for toxicological data, estimation of dietary exposure in consumers, etc.). Again we advise you that at this time your submission does not meet the criterion of a food additive petition. If you intend to prepare an improved petition, please allow us to aid in the preparation of a petition.

Sincerely,

Andrew D. Laumbach, Ph.D.
Division of Petition Review, HFS-215
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Reference List for Industry Submission, GRN 000096

Pages	*Author*	*Title*	*Publish Date*	*Source*	*BIB_Info*
000054-000061	Luo,Jidan; Chen, Kaili; Xu, Qing; Hirabayashi, Kiyoshi	Research leading to Silk Fibroin Protein as a food ingredient/additive/product. Study on Foodization of Fibroin and its functionality	NA	The New Silk Road, Inc.	NA
000062-000066	Hirabayashi, Kiyoshi; Chen, Kaili; Akiyama, Daijiro; Ayub Haider Zuglul	Application of excess silk	NA	SilPRO, Inc.	NA

NA- Not applicable