<table>
<thead>
<tr>
<th>*starch source not identified in methods</th>
<th>Treatment Duration/group</th>
<th>Age of Participants</th>
<th>Qualifying Parameters</th>
<th>Study Design</th>
<th>N/group</th>
<th>Observed variables</th>
<th>Result(s) (significance)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect of cooked rice containing indigestible dextrin on postprandial blood glucose level in healthy human subjects.</td>
<td>Single test meal of steamed rice, incorporated into steamed rice.</td>
<td>39.3 ± 6.8 yr</td>
<td>Healthy male subjects</td>
<td>Cross-over; 3x washout</td>
<td>22 Men</td>
<td>Blood glucose at fasting, 30, 60, 90, and 120 min intervals</td>
<td>No significant difference in postprandial blood glucose levels at 30 min in all subjects when consuming fibersol (p=0.043) compared to control. There was also attenuation of blood glucose levels seen in the subgroup analysis for group H at 30 min and 60 min (p=0.022) compared to control.</td>
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<tr>
<td>Effect of cooked rice containing indigestible dextrin (PineFibre-C) on postprandial blood glucose levels in healthy human subjects.</td>
<td>Single meal loading test- rolls (5 g protein, 2.4 g fat, 17.1 g carb, 190 kcal each) control rolls with or without added Fibersol.</td>
<td>40.1 ± 0.5 yr</td>
<td>Healthy adults</td>
<td>Cross-over; 1 wk washout</td>
<td>33 adults (26 men, 7 women)</td>
<td>Blood glucose measurements collected at 0, 30, 60, and 120 min. Subjects were subgrouped according to the 30 minute serum glucose responses.</td>
<td>Statistically significant decrease in postprandial blood glucose levels at 30 min in all subjects when consuming fibersol (p=0.043) compared to control. There was also attenuation of blood glucose levels seen in the subgroup analysis for group H at 30 min and 60 min (p=0.022) compared to control.</td>
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<tr>
<td>Effect of indigestible dextrin-containing soft drinks on blood glucose levels in healthy human subjects.</td>
<td>Acute meal study using noodles with baked rice, containing 14.1 g protein, 2.8 g fat, 138.6 g of carb, 6.9 kcal with soft drink.</td>
<td>58.3 ± 6.1 yrs</td>
<td>Healthy adult men</td>
<td>Cross-over study</td>
<td>22 men</td>
<td>Serum collected before test meal and 30, 60, and 120 min after ingestion of test meal. Subjects were subgrouped according to the 30 minute serum glucose responses.</td>
<td>There was no significant effect over time between treatment and control when all subjects examined together. Group A (hypoglycemic) results showed treatment significantly suppressed increases in blood glucose only at 30 min (p&lt;0.01). Group B had no significant difference compared to control treatment. The overall treatment group was also analyzed by sex, with men showing a significant improvement in blood glucose at 30 min (p&lt;0.01) compared to control, but there was no effect of treatment in women.</td>
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<tr>
<td>Effect of indigestible dextrin-containing tofu on blood glucose levels in healthy human subjects.</td>
<td>Acute meal study using tofu with or without fibrous added and noodles and rice (10.9 kcal; 100 ml).</td>
<td>30 (15 men and 15 women)</td>
<td>Healthy subjects</td>
<td>Cross-over study</td>
<td>30 (15 men and 15 women)</td>
<td>Serum collected before test meal and 30, 60, and 120 min after ingestion of test meal. Subjects were subgrouped according to the 30 minute serum glucose responses.</td>
<td>There was no significant effect over time between treatment and control when all subjects examined together. Group A (hypoglycemic) results showed treatment significantly suppressed increases in blood glucose only at 30 min (p&lt;0.01). Group B had no significant difference compared to control treatment. The overall treatment group was also analyzed by sex, with men showing a significant improvement in blood glucose at 30 min (p&lt;0.01) compared to control, but there was no effect of treatment in women.</td>
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<tr>
<td>Effects of powdered drink containing indigestible dextrin and young barley leaf powder on postprandial blood glucose level.</td>
<td>Acute Meal test (3 rice balls, 15 g dried fish and vegetable flakes, 7.4 kcal; 150 ml serving)</td>
<td>40.4±11.9 yrs</td>
<td>Healthy subjects</td>
<td>Cross-over study</td>
<td>30 (15 men and 15 women)</td>
<td>Serum collected before test meal and 30, 60, and 120 min after ingestion of test meal. Subjects were subgrouped according to the 30 minute serum glucose responses.</td>
<td>No significant difference in blood glucose levels at any time points. In group H there was a significant attenuation of blood glucose levels at 30 min compared to control (p&lt;0.05). In group L, Fibersol treatment had elevated blood glucose levels at 60 min (p&lt;0.05) compared to control.</td>
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<tr>
<td>Effect of Poredweed Green Tea Containing Indigestible Dextrin on Postprandial Blood Glucose Levels and Safety of its Over ingestion and Long-term Ingestion.</td>
<td>Acute Meal test (9.8 g cooked rice and 2.8 g dried fish and vegetable flakes, 7.4 kcal; 150 ml serving)</td>
<td>35.3 ± 5.9</td>
<td>Healthy adults</td>
<td>Cross-over; 7-d washout</td>
<td>46 (27 Men, 19 Women)</td>
<td>Blood glucose at 0, 30, 60, 90 and 120 min.</td>
<td>Subgroups classified based on blood glucose level 30 minutes after control test meal was 140 mg/dl or above (Group A), or below (Group B). Additional post-hoc analysis was done, separating the subjects by sex.</td>
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<td>Blood glucose at 0, 30, 60, 90 and 120 min.</td>
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</table>
The effect of the intake of freeze dried rice gruel (egg) containing indigestible dextrin on postprandial hyperglycemia and the safety of its long-term intake


4.4 g indigestible dextrin* (PineFiber-C)* administered in one serving of 24 g freeze dried gruel (added 200 ml hot water)

Acute Meal test (300 g rice and 2.5 g fat, 104.8 g carbohydrate; 406 kcal) taken with tea beverage or without PF-C

Healthy adults with fasting blood glucose A<130 mg/dl

Crossover - 1 week washout

20 (18 Men, 2 Women)

Subgroups:

Group H=12, Group L=8

Blood glucose at 0, 15, 30, 60, and 90 min. Postprandial glucose levels were attenuated at 30 minutes by PF-C compared to control meal (p<0.05) in all subjects. In Group H there was a significant reduction also at 30 minutes (p<0.01) and 90 minutes (p<0.05) compared to control. AUC was significantly reduced with treatment compared to control in all subjects and in the High (Group H) group.

Subgroups:

Group H blood glucose > 164 mg/dl (n=10); Group L blood glucose > 164 mg/dl (n=11) after 30min post ingestion of control meal. No AUC data however.


Effect of intake of freeze-dried tomato soup an dHarusame Soup Containing Indigestible dextrin on postprandial hyperglycemia and safety at their long-term intake.


4.4 g indigestible dextrin* (PineFiber-C)* in serving of tomato soup (15.5 g serving; 44kcal)

Acute meal test (300g rice, 9.6g protein, 1.8 g fat, 102 g carbohydrate, 453 kcal) taken with soup or w/o PF-C

Healthy Adults

Crossover study - 7d washout

21 (18 Men, 3 Women)

Subgroups:

Group H=10, Group L=11

Blood glucose and insulin levels at 0, 30, 60, and 120 min. Significant attenuation of blood glucose levels at 30 minutes (p<0.05) in all subjects consuming PF-C compared to control. This same effect was seen in Group H also at 30 minutes, but not Group L. No AUC differences.

Subgroups:

Group H blood glucose > 163 mg/dl (n=10); Group L blood glucose > 163 mg/dl (n=11) (p<0.05) after 30min post ingestion of control meal.


The effect of the intake of green tea beverage and freeze-dried miso-soup (awase-miso) containing indigestible dextrin on inhibition of postprandial hyperglycemia, and the safety of single and long-term intake.


Postprandial hyperglycemia inhibitory effect of single intake of avellanedae tea containing indigstible dextrin and the safety of its long-term intake.


5g indigestible dextrin (PF-C) in a powered tea beverage (160 ml hot water)

Acute meal test (300g rice, 9.6g protein, 1.8 g fat, 102 g carbohydrate, 453 kcal) taken with beverage with or w/o indigestible dextrin

Healthy Subjects

Cross over- 1 day washout

25 12 male 13 female

Subgroups:

Group A=12, Group B=13

Blood Glucose measured at 0, 15, 30, 45, 60, and 120 min intervals.

There was no difference in blood glucose levels between test meal or control (in all subjects) at any particular time point. However, blood glucose AUC for Fibersol tea showed significant lowering in all subjects compared to control tea (p<0.05). Group H did have a statistically significant attenuation of blood glucose by Fibersol at 30 minutes (p<0.01) compared to control.

Subgroups:

Group H blood glucose > 162 mg/dl (n=10); Group L blood glucose > 167 mg/dl (n=11) after 30min post ingestion of control meal. No AUC data however.


The effect of the intake of green tea beverage and freeze-dried miso-soup (awase-miso) containing indigestible dextrin on inhibition of postprandial hyperglycemia, and the safety of single and long-term intake.


Acute Meal test (400g rice with seasoned dried food, 10.3g protein, 3.4 g fat, 138.2g carbohydrate, 626 kcal) with beverage with or w/o indigestible dextrin

Healthy Subjects

Cross over - 3 day washout

25

Blood glucose measured at 0, 15, 30, 45, 60, and 120 min intervals.

There was a significant (p<0.05) attenuation of blood glucose by the miso soup containing Fibersol at 15 min. Also AUC for blood glucose was significantly lower with Fibersol (p<0.05) compared to control. In Group H there was also a significant attenuation of blood glucose levels at 15 (p<0.05) and 30 minutes (p<0.01).

Subgroups:

Group H blood glucose > 167 mg/dl (n=10); Group L blood glucose > 167 mg/dl (n=11) after 30min post ingestion of control meal.


The effect of green tea beverage containing indigestible dextrin on inhibition of postprandial blood glucose elevation and the safety of its long-term use.


Acute Meal Test 200 g of rice with or without PF-C, and cooked noodles (230g; 8.5g protein, 0.8 g fat, 55.3 g carbohydrate, 280 kcal)

Healthy Adults-fasting blood glucose <126 mg/dl

Cross over - 7 d washout

29 (14 Men, 15 Women)

Blood glucose and insulin measured at 0, 30, 60, 90 and 120 min.

There was a significant (p<0.05) attenuation of blood glucose by indigestible dextrin at 30 and 60 min. Also AUC for blood glucose was significantly lower (p=0.017) compared to control. Insulin levels were not significantly affected at any time point.

Subgroups:

Group H blood glucose > 170 mg/dl (n=10); Group L blood glucose > 170 mg/dl (n=13) after 30min post ingestion of control meal. No AUC data however.
Acute meal test of soup with or without indigestible dextrin and meal (3 rice balls 300g, 15 g protein, 1.8 g fat, 123.3 g carb; 565 kcal) 29.5 + 5.6

There was no significant difference in blood glucose levels (all subjects) at any time points. Group H (high BS group) did have a significant attenuation of blood glucose levels at 30 minutes (p=0.05 n=21). No effect in Group L.

Subgroups

- Group H blood glucose > 144 mg/dl (n=23)
- Group L blood glucose > 144 mg/dl (n=22) after 30min post ingestion of control meal. No AUC data provided.

Acute Single dose test meal of soup with or without indigestible dextrin and meal (3 rice balls 300g, 15 g protein, 1.8 g fat, 123.3 g carb; 565 kcal) 29.5 + 5.6

Healthy adults

There were no significant differences in blood glucose levels (subjects) at any time points. Group H (high BS group) did have a significant attenuation of blood glucose levels at 30 minutes (p=0.05 n=21). No effect in Group L.

Blood glucose levels were significantly lower in all subjects at 30 minutes post prandial (p=0.05) with treatment compared to control. Additionally blood glucose level at 30 minutes was significantly lower (p<0.01) in "subjects whose blood glucose levels at 30 minutes after the meal ingestion were higher than their average levels at 30 minutes" (Group A).

Subgroups

- Group A blood glucose < 157.9 mg/dl (n=16) after 30min post ingestion of control meal.
- Group B blood glucose < 157.9 mg/dl (n=22) after 30min post ingestion of control meal.

Blood glucose levels were significantly attenuated by PF-C containing beverage than placebo beverage (p>0.01 and p<0.05 respectively).

Subgroups

- Placebo controlled - 5 AUC data provided.
- Placebo controlled - 5 AUC data provided.

Blood glucose levels were significantly attenuated by PF-C containing beverage than placebo beverage (p>0.01 and p<0.05 respectively).

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- Placebo controlled - 5 AUC data provided.
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Blood glucose levels were significantly attenuated by PF-C containing beverage than placebo beverage (p>0.01 and p<0.05 respectively).

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- Placebo controlled - 5 AUC data provided.
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Blood glucose levels were significantly attenuated by PF-C containing beverage than placebo beverage (p>0.01 and p<0.05 respectively).

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- Placebo controlled - 5 AUC data provided.
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- Placebo controlled - 5 AUC data provided.
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Blood glucose levels were significantly attenuated by PF-C containing beverage than placebo beverage (p>0.01 and p<0.05 respectively).

Subgroups

- Placebo controlled - 5 AUC data provided.
- Placebo controlled - 5 AUC data provided.
Glucose regulation

**Mamani et al. 2004 J. Nutr. Food Res.**
The effects of tea beverages containing indigestible dextrin on postprandial blood glucose level after single intake and safety in continuous intake.

6.0g Fibersol-2* in a blend tea beverage

Acute single dose meal (300g) with or without Fibersol-2 contained in 160 ml of green tea serving of tea

Blood glucose levels were significantly lower (p<0.05) at 30 and 120 min of 116.2±2mg/dl vs 123.2±7mg/dl and 90 min (116.2±2mg/dl vs 123.2±7mg/dl) with treatment compared to control in all subjects. The AUC was also significantly lower (p<0.05) than control in all subjects. Group H blood glucose levels were significantly attenuated at 30 and 60 minutes. AUC for Group H was also significantly lower (p<0.01). No differences in Group L. Serum Insulin levels were also decreased at 60, 90, and 120 min in all subjects.

**Mishita et al. 2004 J. Nutr. Food Res.**
Effect of yogurt containing indigestible dextrin on blood glucose and other blood components.

7.2g Fibersol-2* in yogurt

Acute single dose meal (pastry with jam filling and tea beverage; 11.5 g protein, 5.5 g fat, 12.4 g carb; 583 kcal) and yogurt with or without Fibersol-2 added (~50kcal)

Blood glucose levels at 30, 60, and 120 min after ingestion were also significantly lower (p<0.05) than control in all subjects.

**Fukushima et al. 2002 J. Nutr. Food Res.**
Effects of blend tea containing indigestible dextrin on postprandial blood glucose level and safety of long-term administration.

5g indigestible dextrin (PF-C)* contained in 195g serving of tea

Blood glucose levels at 30 min postprandial were also significantly lower (p<0.05) compared to control tea. There was also a lower trend (p=0.061) at 120 minutes. Blood glucose measurements collected 30 min before ingestion and 30, 60, and 120 min after.

**Kawai et al. 2003 J. Nutr. Food Res.**
The effect of the intake of green tea beverage containing indigestible dextrin on postprandial blood glucose level and the investigation of the safety as its long-term intake.

4.4g indigestible dextrin (PF-C)* contained in 160 ml of green tea.

Blood glucose level at 30 min postprandial was significantly lower (p<0.05) than control (110.6±35.8mg/dl vs 140.5±7.3mg/dl). There is also a lower trend (p=0.061) at 120 minutes.

**Sumi et al. 2003 J. Nutr. Food Res.**
The suppressive effect of the intake of soft drink containing indigestible dextrin on the elevation of postprandial blood glucose level and in safety of its long-term intake.

6.7g Fibersol-2* (cornstarch) in 250ml soft drink (65kcal) compared to soft drink without Fibersol

Blood glucose levels were also significantly lower (p<0.05) at 30 min and 60 min after ingestion compared to control. Blood glucose levels at 30, 60, and 120 min after ingestion were also significantly lower (p<0.05) compared to control.

**Fusse et al. 2002 J. Nutr. Food Res.**
Effect of cooked rice containing indigestible dextrin on postprandial blood glucose level and the safety of eating it long term.

6.4g indigestible dextrin (FineFibre-C)*

Acute single dose meal of semi-aspartic rice with or without indigestible dextrin (4g protein, 0.7 g fat, 53.9 g carb; 240 kcal)

Blood glucose levels at 30, 60, and 120 min after were significantly lower with indigestible dextrin (p<0.05 at all points) compared to meal without indigestible dextrin.

**Manai et al. 2003 J. Nutr. Food Res.**
The effect of cooked rice containing indigestible dextrin on postprandial blood glucose level and the safety of eating it long term.

6.0g Fibersol-2* in a blend tea beverage

Acute single dose meal (300g) with or without cooked rice of 14.8 g fat, 126.6 g protein, 216.1 g carb, 1049.5 g carb; 464 kcal

Blood glucose levels were significantly lower (p<0.05) at 60 minutes (129.2±2mg/dl vs 132.2±7mg/dl) and 90 min (116.2±2mg/dl vs 123.2±7mg/dl) with treatment compared to control in all subjects. The AUC was also significantly lower (p<0.05) than control in all subjects. Group H blood glucose levels were significantly attenuated at 30 and 60 minutes. AUC for Group H was also significantly lower (p<0.01). There was also a lower trend (p=0.061) at 120 minutes.

**Mishita et al. 2004 J. Nutr. Food Res.**
Effect of yogurt containing indigestible dextrin on blood glucose and other blood components.

7.2g Fibersol-2* in yogurt

Acute single dose meal (pastry with jam filling and tea beverage; 11.5 g protein, 5.5 g fat, 12.4 g carb; 583 kcal) and yogurt with or without Fibersol-2 added (~50kcal)

Blood glucose levels at 30, 60, and 120 min after ingestion were also significantly lower (p<0.05) than control in all subjects.

**Fukushima et al. 2002 J. Nutr. Food Res.**
Effects of blend tea containing indigestible dextrin on postprandial blood glucose level and safety of long-term administration.

5g indigestible dextrin (PF-C)* contained in 195g serving of tea

Blood glucose levels at 30, 60, and 120 min after ingestion were also significantly lower (p<0.05) compared to control tea. There was also a lower trend (p=0.061) at 120 minutes.

**Kawai et al. 2003 J. Nutr. Food Res.**
The effect of the intake of green tea beverage containing indigestible dextrin on postprandial blood glucose level and the investigation of the safety as its long-term intake.

4.4g indigestible dextrin (PF-C)* contained in 160 ml of green tea.

Blood glucose levels at 30 min postprandial were also significantly lower (p<0.05) than control (110.6±35.8mg/dl vs 140.5±7.3mg/dl). There is also a lower trend (p=0.061) at 120 minutes.

**Sumi et al. 2003 J. Nutr. Food Res.**
The suppressive effect of the intake of soft drink containing indigestible dextrin on the elevation of postprandial blood glucose level and in safety of its long-term intake.

6.7g Fibersol-2* (cornstarch) in 250ml soft drink (65kcal) compared to soft drink without Fibersol

Blood glucose levels were also significantly lower (p<0.05) at 30 min and 60 min after ingestion compared to control. Blood glucose levels at 30, 60, and 120 min after ingestion were also significantly lower (p<0.05) compared to control.

**Fusse et al. 2002 J. Nutr. Food Res.**
Effect of cooked rice containing indigestible dextrin on postprandial blood glucose level and the safety of eating it long term.

6.4g indigestible dextrin (FineFibre-C)*

Acute single dose meal of semi-aspartic rice with or without indigestible dextrin (4g protein, 0.7 g fat, 53.9 g carb; 240 kcal)

Blood glucose levels at 30, 60, and 120 min after were significantly lower with indigestible dextrin (p<0.05 at all points) compared to meal without indigestible dextrin.
Acute study using test meal containing rice cake (16.5 g protein, 3.9 g fat, and 130.4 g carb, 615 kcal) in product containing 67.5 g corn syrup solids (from potato starch) in 225 ml beverage with 75 g of glucose tolerance test (acaloric (75 g glucose load) 30.0 ± 1.5 Healthy adult men cross over study - 1 week washout period 6 men venus blood collected at 0, 30 and 60 minutes; urine also collected at 2 hrs to examine U-CPR levels. All treatment groups reached peak blood glucose levels, but levels were lower with any of the fiber treatments.


Ueda et al 1993 J Japan Diab Soc 36:715-723

Effects of indigestible dextrin on blood glucose and urine C-peptide levels following sucrose loading

3.6, or 30 g PP-C (from potato starch) test drink oral sucrose loading test (30g sucrose challenge in 100 ml carbonated water) 35.0 ± 2.4 Healthy adult men cross over study - 1 week washout period 6 men venus blood collected at 0,30 and 60 minutes ; urine also collected at 2 hrs to examine U-CPR levels. All treatment groups reached peak blood glucose levels, but levels were not lower with any of the fiber treatments.

Improvement of Glucose Tolerance by Low-Viscosity, Water-Soluble Dietary Fiber, Indigestible Dextrin 2001 Nutrition Research 21: 1099-1106


Wakabayashi 1992 Folia Endocrinol 68: 623-635

31

Shimohara et al 1999 J Nutritional Food 2(1): 52-56

Effects of indigestible dextrin-containing green tea on blood glucose level in healthy human subjects.

There was no significant effect over time between treatment and control when all subjects examined together. Group A (hyperglycemic) results showed treatment significantly suppressed increases in blood glucose only at 30 minutes (p<0.05), however AUC was not significantly different. Subgroups classified based on blood glucose level 30 minutes after control test meal was 155 mg/dl or above (Group A), or below (Group B). The peak change from baseline in blood glucose was not significantly different between groups. The incremental AUC of blood glucose did not differ between treatments. Postprandial incremental change from baseline did not differ between treatments across all time points. Relative glycemic responses was calculated to be 101.6 ± 5.3 indicating that indigestible dextrin had no effect on the postprandial glycemic meal response of partially hydrolyzed corn starch. Excellenty designed and conducted study! Subject’s meals were controlled for 3 days leading up to the testing period, with the meal before the overnight fast being specifically adjusted to each subject’s energy requirement.

Efficacy of tea drink containing indigestible dextrin* Pine Fiber L (PF-L) in 225 ml beverage with 75 g of glucose containing 2.5 g fat, 13 g protein, 140 g carb, and 634 kcal added. There was no significant change in blood glucose AUC.

Fujikawa et al 2000 J of Nutrition Food 3(1): 65-72


Kawasaki et al 1999 J of Nutrition Food 3(1): 65-72

Efficacy of tea drink containing indigestible dextrin* Pine Fiber L (PF-L) in 225 ml beverage with 75 g of glucose containing 2.5 g fat, 13 g protein, 140 g carb, and 634 kcal added. There was no significant change in blood glucose AUC.

Kishimoto et al. 2007 Eur J Nutr 36:8-26

Suppressive effect of resistant maltodextrin on postprandial blood triacylglycerol elevation.

There were disagreements between tablet 2 and the text in the translated paper. Also there was sub grouping of subjects based on glucose response (group A had 14 subjects, group B 16 subjects).

Glucose regulation Page 5
Takakusaki et al. 2001 J Nutr. Food Sci 51(2) 19-27
Effect of a tea beverage containing indigestible dextrin on the blood glucose level after ingestion of starchy food

6.9g indigestible dextrin (PineFiber-C)* contained in 190 g of corn tea with vitamin C.

Single meal of 300 g of rice and dried food (6.9g protein, 1.8 g fat, 102 g carb; 453 kcal) and test drink with or without test material

Subgroups
Group H: 17 men, 6 women
Group L: 14 men, 7 women

Blood glucose at 30 minutes was not significantly different for all subjects. No difference in AUC either. In group H; blood glucose was attenuated at 30 minutes (p<0.05) compared to placebo.

Subgroups: Group H blood glucose > 152.1 mg/dl; Group L blood glucose < 147.9 mg/dl

Moriguchi et al. 2004 Japan Innovative Food Ingredients Research (1) 59-67
The suppressive effect of the intake of beverage containing indigestible dextrin on the rise of postprandial blood glucose level

5g indigestible dextrin (PineFiber-C)* contained in 250ml soft drink

Single meal test (300 g rice and 200 g of wheat noodle (13.1g protein, 5.2 g fat, 164 g carb, 634 kcal), and test drink with or without test material

Subgroups
Group H: 21 men, 15 women
Group L: 14 men, 3 women

Blood glucose was significantly lower (p<0.05) at 30 min in the test beverage(144.6mg/dl) than the control beverage(150.5mg/dl) in all subjects. In subjects which had a higher glycemic response (n=12), there was also a significant effect at 60 minutes, but this was not seen with the entire study population.

Subgroups: Group H blood glucose > 147.9 mg/dl (n=23); Group L blood glucose < 147.9 mg/dl (n=22) after 30min post ingestion of control meal. No AUC data.

Effect of black tea containing indigestible dextrin on post-prandial blood glucose levels and safety of long-term administration

6.2g FiberSol-2 and powdered black tea extract in 150ml warm water

Single meal test; 300g steamed rice (126.8g carb; 592 kcal) and egg soup (26 kcal); and tea beverage with Fibersol-2 (test) or Maltodextrin (placebo) 33.6+1.01

Subgroups
Group H=25
Group L=24

Blood glucose was measured before meal and after 15, 30, 60, and 120 min. of ingestion

Blood glucose was significantly lower (p<0.05) at 30 min in the test beverage(144.6mg/dl) than the control beverage(150.5mg/dl) in all subjects. In group H, blood glucose levels were lower at 15 and 30 min(>0.05).

Subgroups: Group H blood glucose > 152.5 mg/dl (n=24) after 30min post ingestion of control meal. No AUC data however.

Effects of indigestible dextrin on postprandial rise in blood glucose levels in man.

7 g Fibersol-2 (from corn starch) in 100 ml coffee

Sweet roll and bean jam loading; 13g protein, 5 g fat, 114 g carb, 553 kcal. Test drink was 100 ml of coffee with or without fibersol.

Subgroups
Group H=20
Group L=19

Blood glucose levels were significantly lower (p<0.05) at 30 minutes after non-treated control, but not different at any other time point.

No AUC data.

Glucose regulation
Effects of indigestible dextrin containing soft drinks on postprandial blood glucose levels in healthy human subjects
7.0 g PF-C* dissolved in tea drink (160 ml serving) (6 kcal) Control drink had maltodextrin in place of test material. 37.7 ± 10.0 Healthy subjects cross over study- 7 d washout 25 (12 men, 13 women) Subgroups:
Group H *11, Group L*14
Blood glucose levels at 0, 30, 60, and 120 minutes. Analytical data of the data from all subjects, no difference was found between PF-C and control at any time. However dividing the subjects into two groups; Group H had attenuated serum glucose levels at 30 min postprandial (p<0.05). Subgroups: Group H (n=11) blood glucose < 166 mg/dl Group L (n=14) blood glucose > 166 mg/dl

Effects of indigestible dextrin in tea drink (160 ml serving) (6 kcal)
Subgroups: Group H (n=11) blood glucose > 166 mg/dl Group L (n=14) blood glucose < 166 mg/dl

Shioda et al. 2001 J Nutritional Food 4(2): 7-18
Effects of yogurt drink containing indigestible dextrin on postprandial blood glucose levels in Japanese healthy volunteers
7.9 g PF-C* in 180 ml yoghurt drink (81.9 kcal) cross over study- 1 week wash out periods 40 (32 Men, 8 Women) Subgroups:
Group A*20
Group B*20
Blood glucose measured at 0, 30, 60, and 120 minutes. Blood glucose levels were significantly lower with fibersol (p<0.05) at 30 minutes compared to non-treated control, but not different at any other time point. No AUC data. Small number of subjects.

Fujiwara et al. 1995 J Clin Nutr 83:301-305
Continuous administration tests of indigestible dextrin; II: study on the effects of the improvement of fat metabolism in patients with non-insulin-dependent diabetes mellitus. 30 g/day indigestible dextrin with meals (30 g/day) dissolved in 100 ml water (potato starch) 16 weeks 54.8 yrs (41-68) Insulin resistant diabetics (NIDDM) uncontrolled study 5 men, 2 women body weight, blood pressure, and blood and urine collected (2 at baseline, and then at weeks 4, 8, 12, and 16). No significant changes from baseline in fasting blood glucose, fructosamine, HbA1, and HbA1c level. Kolone studies showed a tendency to decreases with treatment. Some patients may have had lower fasting blood sugars after one to 3 months of treatment, however there were no statistics to indicate significance. AUC data was highly variable between individuals. Small sample size 4 out of 5 subjects were also on medicine; Meal test consisted of sliced toast, milk and salad (459 kcal total).
Glucose regulation

**Effects of green tea beverage containing indigestible dextrin on the suppression of postprandial blood glucose elevation and the safety of its long-term use**

  - 20g/day indigestible dextrin PF-C* (6.7g/serving 3x/dl)
  - 12 weeks
  - 20 males, 18 females
  - Physical measurements, serum cholesterol, serum chemistry, and CBC
  - Uncontrolled study

**Effects of blend tea containing indigestible dextrin on postprandial blood glucose level and safety of long-term administration**

  - 15g/day indigestible dextrin* (150g serving of blend tea with 5g indigestible dextrin 3x/d with meals)
  - 13 weeks
  - 33.4±1.8yrs
  - Healthy male subjects
  - Uncontrolled study

**Effects of cooked rice containing indigestible dextrin on postprandial blood glucose level and the safety of eating it in long-term in**

  - Semi-aseptic packaged rice containing (total dietary fiber >7.5g)
  - 6.6g indigestible dextrin(PowFibre-C)* 3 times per day= 20.4g/d
  - 12 weeks
  - 40.8±6.2
  - 10 men
  - Physical measurements, serum cholesterol, serum chemistry and CBC

**Effects of black tea containing indigestible dextrin on postprandial blood glucose level and safety of long-term administration**

- **Hori et al. 2005 J. of Nutr. Food 7(2), 27-35**
  - 18.6g Fibersol-2* (6.2g Fibersol-2* and powdered black tea extract in 150ml warm water, taken 3x/d with meals)
  - 12 weeks
  - NA
  - Healthy subjects
  - Uncontrolled study

**Effects of soup powder containing indigestible dextrin on postprandial blood glucose level and safety of long-term intake**

  - 15.3g Fibersol-2* (3 servings/d of 5.1 g in soup)
  - 12 weeks
  - 37.1±9.4
  - Healthy adults
  - Uncontrolled study

**Effects of powdered drink containing indigestible dextrin and young barley leaf powder on postprandial blood glucose level**

- **Ito et al. 2006 Jpn Pharmacol Ther 34(8) 945-952**
  - 8g Fibersol-2* (4g = 2x/d) on evening of postprandial blood glucose level and safety in long-term ingestion
  - 12 weeks
  - 33.6±5.8yrs
  - Healthy adults
  - Uncontrolled study

**Effect of powdered drink containing indigestible dextrin and young barley leaf powder on postprandial blood glucose level**

- **Kajimoto et al. 2000 J. Nutritional Food 3(3), 47-58**
  - 16.5g Fibersol (in a 250 ml total drink, 3 times per day 5.5g indigestible dextrin per bottle)*
  - 4 weeks
  - 35±10.4 yrs
  - Minit hyperglycemic men (150-250 mg TG/dl)
  - Randomized, placebo controlled study

**Beneficial effects of a new indigestible dextrin-containing beer on lipid metabolism and obesity-related parameters**

- **Koizumi et al. 2001 J. Nutritional Food 5(3), 47-58**
  - 10= test grp
  - 8= placebo
  - Phsyologic examination and serum tested before run in, after 2 week run in (baseline), after 4 weeks of treatment, and then after 2 weeks of wash out
  - Fasting blood glucose levels were decreased compared to baseline, however this was not different from control. Fairly well done study, would be stronger with additional subjects

**No significant changes in fasting blood glucose levels with treatment. HbA1c levels were significantly higher at week 4 and 8. Although the changes were statistically significant the levels were within a normal range.**

  - There were no significant changes in HbA1c levels.
  - Uncontrolled study

**No significant changes in fasting blood glucose level and safety of eating it in long-term in**

  - There were no significant changes in fasting blood glucose levels.
  - Uncontrolled study

**No change in fasting blood glucose levels or HbA1c during testing period.**

  - No change in fasting blood glucose levels or HbA1c during testing period.
  - Uncontrolled study

**Percentage body fat was reduced significantly (p<0.01) from baseline (20.6% to 19.1%) after 13 weeks. Blood glucose was significantly reduced from baseline at 8 weeks, but this did not persist. In liver, kidney, and electrolytes all the data are in the standard range and there were no meaningful changes.**

  - Percentage body fat was reduced significantly (p<0.01) from baseline (20.6% to 19.1%) after 13 weeks. Blood glucose was significantly reduced from baseline at 8 weeks, but this did not persist. In liver, kidney, and electrolytes all the data are in the standard range and there were no meaningful changes.
  - No AUC data provided; small sample size, uncontrolled study.
Glucose regulation

Kajimoto et al. 2001 J. of Nutritional Food 4(2) Safety of a long-term intake of a tea beverage containing indigestible dextrin. 18.3 g/d indigestible dextrin (PineFiber-C)* (6.1 g serving contained in a 250 ml tea beverage) 12 weeks 29.2 ±5.2 Healthy adult subjects uncontrolled study 16 Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks Fasting blood glucose levels were no changed from baseline. There were some statistically significant changes in HbA1c levels but they were not clinically relevant changes - within a normal range. Uncontrolled study, limited subjects.

Kajimoto et al. 2002 J. Nutritional Food 5(3): 117-130 Effects of a tea beverage containing indigestible dextrin on the serum triglyceride levels in subjects with mild hypertriglyceridemia. 16.5 g PF-C (6.5 g of indigestible dextrin (250 ml serving of tea) (PF-C)* 8 weeks 48.2±11.2 yrs (range 26-69) men with mildly elevated serum triglycerides (>150 mg/dl, <400 mg/dl) placebo controlled, double blind study 45 total completed (23-real grp 22-placebo grp) a total of 8 blood tests were taken, at 4 week intervals. Chem 21, RBC and white count, also blood pressure and physical measurements taken No significant change in fasting blood glucose levels or HbA1c levels compared to control. study design included a 4 week run in phase and a 4 week post ingestion wash out phase in addition to the 8 weeks of treatment. Well done and reported study.

Kawai et al. 2002 J. Nutr. Food 5(3): 117-130 The effect of the intake of green tea beverage and freeze-dried miso-soup (awa-miso) containing indigestible dextrin on inhibition of postprandial hyperglycemia, and the safety of single and long-term intake. 17.7 g Fibersol-2* (5.9 g Fibersol-2 taken with meals 12 weeks 41.2 ± 2.2 Healthy adult subjects uncontrolled study 19 Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks Fasting blood glucose levels were unchanged with consumption of green tea containing Fibersol-2. There were no significant changes in fasting blood glucose or insulin levels with treatment. HbA1c levels were significantly lower at week 8 and 12, although the changes were statistically significant the levels were within a normal range. Uncontrolled Study

Kawai et al. 2002 J. Nutr. Food 5(4): 33-45 The effect of the intake of green tea beverage and freeze-dried miso-soup (awa-miso) containing indigestible dextrin on inhibition of postprandial hyperglycemia, and the safety of single and long-term intake. 17.7 g indigestible dextrin (PF-C)* (5.9 g PF-C serving of 175 ml of green tea) 12 weeks 36.8 ± 7.3 Healthy Subjects uncontrolled study 11 (9 Men, 2 Women) physical measurements, serum cholesterol, serum chemistry and CBC. Fasting blood glucose levels were unchanged with consumption of green tea containing Fibersol-2. HbA1c levels were statistically higher at week 4, but not a clinically relevant amount. uncontrolled study with limited subjects

Kawai et al. 2002 J. Nutr. Food 5(4): 33-45 The effect of the intake of freeze-dried miso-soup (white miso) and Japanese clear soup both containing indigestible dextrin on inhibition of postprandial hyperglycemia and the safety of their long-term intake. 13.2 g indigestible dextrin (PF-C)* (4.4 g PF-C serving of 160 ml of miso soup) 12 weeks 35.8 ± 5.4 Healthy Subjects uncontrolled study 11 (10 Men, 1 Woman) physical measurements, serum cholesterol, serum chemistry and CBC. The miso soup containing PF-C resulted in statistically significant decreases in fasting blood glucose levels at 8 and 12 weeks (90 and 89 mg/dl each) compared to baseline (93 mg/dl) (p<0.05). No significant change in HbA1c levels during study. uncontrolled study with limited subjects

Kawai et al. 2003 J. Nutr. Food 6(2): 129-139 The effect of the intake of freeze-dried miso-soup (white miso) and Japanese clear soup both containing indigestible dextrin on inhibition of postprandial hyperglycemia and the safety of their long-term intake. 13.2 g indigestible dextrin (PF-C)* (4.4 g PF-C serving of 160 ml of miso soup) 12 weeks 34.4 ± 8.2 yr Healthy Subjects uncontrolled study 11 (9 Men, 2 Women) Blood and Urine tests before intake and after 4, 8, and 12 weeks No significant change in fasting blood glucose levels or HbA1c levels during study. uncontrolled study with limited subjects

Kawai et al. 2005 Health Science 21(1) 61-68 Effects of a tea beverage containing indigestible dextrin on postprandial hyperglycemia and the safety at its long-term intake. 13.2 g indigestible dextrin* (1 serving/9g of 4.4g PineFiber-C contained in 24 g freeze dried green tea) 12 weeks 33.2 ± 7.3 Healthy adults with fasting blood glucose >200 mg/dl uncontrolled study 11 (10 Men, 1 Woman) Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks No changes in fasting blood glucose or HbA1c during the trial period. uncontrolled study with limited subjects

Glucose regulation
Glucose regulation

Effect of intake of Freeze-dried tomato soup and Harusame Soup containing indigestible dextrin on postprandial hyperglycemia and safety at their long-term intake.

13.2 g/d indigestible dextrin* (PineFiber-C) (4.4 g/serving of tomato soup (15.5 g serving; 44 kcal) taken 3x/d) 12 weeks
Healthy Adults uncontrolled study
Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks
No effect seen on fasting blood glucose or HbA1c levels. uncontrolled study with limited subjects

Efficacy of tea drink containing indigestible dextrin

18.75 g/d (6.25 g of indigestible dextrin (PF-C) in 190 g serving of tea/meal) 12 weeks
Healthy subjects with slightly elevated blood glucose level or family history of diabetes uncontrolled study 9 (4 men, 5 women)
Fasted blood sample for serum measures of lipids, chem 21 panel, and blood glucose taken at 4 week intervals
No effect seen on fasting blood glucose levels. Small number of subjects, and no control group. (second study included in previous report)

Kishimoto et al. 2000 J Nutritional Food 3(2) 19-27
Effects of instant miso-soup containing indigestible dextrin on moderating the rise of postprandial blood glucose levels and safety of long-term administration

13.5 g/d (4.5 g/d of indigestible dextrin (PF-C) in miso-soup/meal x 3/d) 12 weeks
Hyperglycemic subjects uncontrolled study
Fasted blood sample for serum measures of lipids, chem 21 panel, and blood glucose taken at 4 week intervals
No impact on fasting blood glucose levels or HbA1C at any point in the study. Small number of subjects, and no control group.

Kishimoto et al. 2000 J Nutritional Food 3(3) 19-27
Effects of a long-term administration of indigestible dextrin

30 g/d (10 g indigestible dextrin with meals 3x/d) dissolved in water (cornstarch based) 12 weeks
Total serum cholesterol level >200 mg/dl or TG of >150 mg/dl (all men) uncontrolled study 12
Fasted blood sample for serum measures of lipids, chem 21 panel, CBC and blood glucose taken at 4 week intervals
Period compared to baseline. However a glucose tolerance test conducted at baseline and end of study showed a significant improvement from baseline for the 30, 60 and 120 minute time points (P<0.05 at 30 and 120; P<0.01 at 60 min). No significant improvement in insulin response seen.

Manami 2004 Japan Inn. Food Ing. Research 7(1) 83-93
The effects of tea beverages containing indigestible dextrin on postprandial blood glucose level after single intake and safety in continuous intake

18.5 g/d Fibersol-2* (6 g/serving in blended tea beverage taken 3x/d) 12 weeks
Healthy Subjects uncontrolled study 15
Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks
There were no significant changes in fasting blood glucose or insulin levels with treatment. HbA1c levels were significantly lower at week 8 and 12; although the changes were statistically significant the levels were within a normal range. uncontrolled study with limited subjects

Mizutani et al. at 2000 J Nutritional Food 3(3): 75-82
Effect of long-term ingestion of indigestible dextrin-containing soft drinks on safety and blood glucose levels.

29.4 g/d (9.8 g of PF-C/100 ml soft drink) 12 weeks
Borderline hyperglycemic male subjects (fasting blood glucose >110 mg/dl) uncontrolled study 10
Blood tests, UA, and health checks at 0, 4, 8, 12 weeks during treatment and then again post-treatment after 8 weeks
Fasting blood glucose levels were significantly decreased compared to baseline over the course of the study (P<0.01). Fructosamine levels were also significantly decreased over time. No change in HbA1c. uncontrolled study with limited subjects
There were no significant differences between baseline and any time points for fasting blood glucose levels, HbA1c, or insulin. Uncontrolled Study.
A green tea powder containing indigestible dextrin had an effect on postprandial blood glucose level and the safety of long-term intake. Tamura 2003 J. of Nutr. Food 69(3) 55-63

19.2g indigestible dextrin (PF-C)* taken as 6.4g (PF-C)/120 ml serving 3x/2d: 12 weeks 462±2.3 2 Healthy Subjects and 8 subjects who had higher postprandial blood glucose levels uncontrolled study 10 males Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks There were no significant differences in fasting blood glucose or HbA1c compared to baseline observed. uncontrolled study with limited subjects


17.1g Fibersol-2; 5.7 g/190 g bottle of green tea beverage (2 kcal); control drink was tea alone without Fibersol taken 3 times per day with meals 12 week yea healthy subjects uncontrolled study 16 (9 men and 7 women) fasting blood samples collected at baseline, 4, 8, and 12 weeks No change in fasting blood glucose levels during the course of the study in either men or women. There was an increase in HbA1C noted at 4 and 8 weeks which was significant compared to baseline (P=0.01), however authors state this change was still within a normal range of variation, thus not clinically relevant. Small sample size confounded by the data being expressed separately for men and women, thus statistical analysis was performed on small sample size (n=9 or 7).

A scientific approach to health preservation medicine the result and the safety on the long-drinking tea contained indigestible dextrin against borderline diabetes group Ying et al. 2000 Eastern Medicine vol. 16, No. 1, p11-16

16g indigestible maltodextrin* in RY Tyroo tea (10g tea to 200g boiled water; with or w/o 8g indigestible dextrin) (2x/d w/meals) 6 months 49.6±14.1 y Plasma glucose levels were significantly lower than the positive control (50 g glucose) at 30 and 60 min. Plasma insulin was also lower compared to the positive control. limited study - tested compared to maltodextrin Small Sample size: study subjects were treated for 6 months with indigestible dextrin then had an acute glucose response to a test meal with or without treatment material.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>Type</th>
<th>Fibersol dose (source)</th>
<th>Treatment Duration/group</th>
<th>Age of Participants</th>
<th>Qualifying Parameters</th>
<th>Study Design</th>
<th>N/group</th>
<th>Observed variables</th>
<th>Result(s) (significance)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ohkuma et al. 1990 Denpun Kagaku 37:107-114</td>
<td>Purity of starch and its digestibility by enzymes-Characterization of indigestible dextrin</td>
<td>1</td>
<td>20g indigestible dextrin (from potato starch) (P3)</td>
<td>Acute ingredient only test</td>
<td>Healthy male subjects</td>
<td>Cross over study</td>
<td>3</td>
<td>Blood glucose and insulin at 0, 30, 60, 90 and 120 min.</td>
<td>There was no appreciable rise in serum glucose or insulin with this fraction treatment (Fibersol-2), however it did not appear that the significance was able to be determined. This was compared to maltodextrin (20g).</td>
<td>Limited study - tested compared to maltodextrin</td>
<td></td>
</tr>
<tr>
<td>Ohkuma et al. 1990 Denpun Kagaku 37:107-114</td>
<td>Purity of starch and its digestibility by enzymes-Characterization of indigestible dextrin</td>
<td>2</td>
<td>50g indigestible dextrin (from potato starch) (P1)</td>
<td>Acute ingredient only test</td>
<td>Healthy male subjects</td>
<td>Cross over study</td>
<td>5</td>
<td>Blood glucose and insulin at 0, 30, 60, 90 and 120 min.</td>
<td>Plasma glucose levels were significantly lower than the positive control (50 g glucose) at 30 and 60 min. Plasma insulin was also lower compared to the positive control.</td>
<td>Limited study - tested compared to glucose</td>
<td></td>
</tr>
<tr>
<td>Okuma and Matsuda 2002 J Appl Glycosci 49(4) 479-485</td>
<td>Indigestible Fractions of Starch Hydrolysates and their determination method</td>
<td>3</td>
<td>50g indigestible dextrin (Fraction H + Fibersol) in a 35% solution</td>
<td>Acute ingredient only test</td>
<td>Healthy male subjects</td>
<td>Cross over study</td>
<td>5</td>
<td>Blood glucose and insulin at 0, 30, 60, 90 and 120 min.</td>
<td>There was no significant rise in serum glucose or insulin levels by the test substance (Fraction H). Serum glucose and insulin levels were both significantly lower through the time course compared to the positive control oral dose glucose (p&gt;0.01)</td>
<td>Limited study - comparisons with glucose, maltodextrin, and various fractions from the production of Fibersol were examined. AUC data provided.</td>
<td></td>
</tr>
<tr>
<td>Kandea et al 2005 J. Innovative Food Ingredients Research 8(2): 119-124</td>
<td>Effect of Intake of Powdered Green Tea Containing Indigestible Dextrin on Postprandial Blood Glucose Levels and Safety of Its Over-ingestion and Long-term Ingestion</td>
<td>4</td>
<td>19.8 g (3 servings of green tea, each containing 6.6 g Fibersol-2)</td>
<td>Acute ingredient only test</td>
<td>Healthy adults, fasting blood glucose levels were less than 110mg/dl and postprandial blood glucose level was over 140 mg/dl (borderline hyperglycemia group)</td>
<td>Uncontrolled study</td>
<td>10 (3 Men, 7 Women)</td>
<td>Blood glucose and insulin levels at 0, 30, 60, and 120 min.</td>
<td>There were no changes in blood glucose or insulin with ingredient challenge.</td>
<td>Beverage only, not a meal challenge. Beverage contained: 6.6 g Fibersol-2/ 0.35 g powdered green tea, 0.225 green tea extract, 0.225 Roasted tea extract, and 0.09375 chlorella (3.75g serving) dissolved in 100 ml of hot water serving.</td>
<td></td>
</tr>
</tbody>
</table>
| Shoya 2004 J. of Nutr. Food 74(3) 31-41 | The inhibitory effect on the postprandial increase in blood glucose exerted by powdered beverage containing indigestible dextrin and its safety in over-ingestion and long-term ingestion | 5 | 24.8 g Fibersol-2 (from 3-8.2g Fibersol-2* in powdered beverages dissolved in 300 ml) | Acute ingredient only test | Healthy Subjects | Uncontrolled study | 11 | Blood glucose and insulin measurements at 0, 30, 60, 90, and 120 min after ingestion | There were no changes in blood glucose or insulin with ingredient challenge. | Beverage only, not a meal challenge. Beverage contained: 8.2 g Fibersol-2, 0.20 g Grifola frondosa, 0.15 g powdered plum extract, and 1.45 g lacrosse.