



Scientific Support Document
Fruitables® Pumpkin SuperBlend™ **Weight Loss Supplement**



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Fruitables® Pumpkin SuperBlend™ Weight Loss Supplement

Scientific Support Document of Application for Weight Control

Introduction

Obesity is the most common nutritional disorder affecting dogs in the United States. In fact, it has been estimated that up to 40% of dogs are overweight or obese. Obesity is defined as an accumulation of excess body fat resulting in body weights of more than 15-20% of optimum. These conditions can potentially impair the health, quality of life, and life span of affected pets.

Weight gain occurs when there is an imbalance between intake and expenditure of calories. The primary cause is excessive food intake and inadequate exercise. The incidence of obesity increases with age and neutering because there is a reduction of both metabolic rate and physical activity.^{1 2}

Some breeds of dogs like Labrador retrievers, dachshunds, miniature schnauzers, Welsh corgis, cocker spaniels, and beagles seem to be genetically predisposed to excessive weight gain. Obese adult dogs are more likely to be diagnosed with hypothyroidism, diabetes mellitus, pancreatitis, or neoplasia.³ Other disease conditions that may be associated with excess weight in dogs include hyperadrenocorticism, hypertension, circulatory problems, and decreased resistance to infection. Overweight dogs are also predisposed to joint and locomotor problems including osteoarthritis, ruptured cruciate ligaments, dyspnea and fatigue, impaired reproductive efficiency, and dystocia.^{3 4}

Weight Management

Pet owner compliance is essential to a successful weight reduction program. Prior to initiation of a weight control program, the overweight animal should have a thorough physical examination by its veterinarian. At that time the veterinarian will estimate the animal's ideal, or target, body weight. An ideal goal for weight loss is approximately 1-2% of current body weight per week. This rate appears to help maximize the amount of adipose tissue loss while maintaining lean body mass.

Cats should be monitored closely because rapid weight loss can lead to hepatic lipidosis, a potentially fatal fatty infiltration of the liver.^{5 6}

Even though a dog or cat on a weight reduction program should receive a restricted amount of calories, they still need optimal amounts of other nutrients such as protein (high quality-- with essential amino acids), vitamins, and minerals. Weight loss may actually increase the need for these nutrients so the use of weight management or weight loss diets and/or supplements may be preferred.

Increased amounts of dietary fiber, may reduce the rate of digestion and absorption, and may

¹ Bauer, J.E. 2005. Nutrition: Small animals. In: The Merck Veterinary Manual. vol.9. ed. Kahn, C.M., Merck-Merial Ltd, Philadelphia, p. 1932-1933.

² Flynn, M. et al. 1993. Effect of ovariohysterectomy on maintenance requirements of cats. JAVMA. 209:9. p 1572-1581.

³Lund, E. M. et al. 2006. Prevalence and risk factors for obesity in adult dogs from private US veterinary practices. Int J App Res Vet Med. 4: 77-186.

³⁴ Norris, M. et al. 1993. Application of behavior therapy techniques to the treatment of obesity in companion animals. JAVMA. 202:5. p 728-730.

⁵ Lewis, L. et al. 1987. Obesity. In: Small Animal Clinical Nutrition III. Mark Morris Associates. Topeka. p 6:2-6:36.

⁶ Burkholder, W. et al. 1998. Foods and techniques for managing obesity in companion animals. JAVMA. 212:5. p 658-662.

assist in increasing the level of satiety in the dieting pet.⁷ Feeding obese dogs a high-fiber food resulted in reduced caloric consumption, reduced body weight, and a 3.3% reduction in body fat, whereas feeding a low-fiber food resulted in a comparable increase in caloric consumption and a 2.4% gain in body fat. These results suggest that the addition of dietary fiber to foods may be helpful in the treatment of canine obesity. Adding supplemental fiber while ensuring that the remaining diet is not unbalanced may therefore be an important strategy for canine weight loss.

Diets enriched in dietary fiber are naturally lower in calories on a per ounce basis. As such they can provide satiety as well as the necessary calorie reduction for healthy weight loss and weight management while reducing the perception of hunger.

Fruitables® Pumpkin SuperBlend™ Weight Loss Supplement is a nutritional food supplement product designed to be fed in conjunction with decreased amounts of calorie controlled foods. It has been specially formulated and developed to be fed together with measured amounts of existing, commercially available, complete and balanced, pet foods. When fed together according to label instructions, calorie reduction occurs to a level where weight loss will occur, allows for a larger volume of food to be consumed contributing to satiety, yet meets all nutritional needs for healthy weight management or weight reduction. This approach is a valuable strategy for long-term weight control.

Fruitables®

Fruitables® is made from fresh vegetables that are naturally low in calories (279 Kcal/kg) and fat (2.8% dry matter) and high in fiber (23% dry matter). Fruitables also contains 11% protein on dry matter basis in a highly palatable pumpkin flavor that assures that dogs will eat the amounts offered while reducing their total daily caloric intake for weight management. It is also high in β-carotene which has been shown to promote a healthy immune system in dogs, including older dogs. Older dogs are often overweight or obese and thus will additionally benefit by having Fruitables supplement added to their daily diet. It is formulated to be fed, as recommended, in combination with prescribed amounts of existing complete and balanced diet. Instead of feeding one cup of a recommended dry dog food; use 2/3 cup (about 70%) of the dry food plus approximately 1/3 can (about 30%) of Fruitables® (15 oz can). This feeding instruction is easy to follow and is all that is needed to lower caloric intake by that amount most frequently recommended by veterinarians for healthy weight loss. The label shows feeding instructions to be used for dogs' starting obese body weights. The ratio of 70% complete and balanced food and 30% Fruitables® should be used as a general rule when feeding for animals whose present body weights are not specifically indicated on the label feeding instructions. These amounts will assure that all nutritional requirements are met. The following brands have been evaluated and have been recommended for use so that nutritional balance is assured:

<u>Specialty Pet Store Brands/Kcal per kg</u>	<u>Mass Marketed Brands/Kcal per kg</u>
● Innova® Low Fat Adult Dry Dog Food 3,340	● Hill's Science Diet® Light Adult 2,949
● Wellness Super5Mix® Healthy Weight	● Iams Weight Control™ 3,853
● Eagle Pack Adult Reduced Fat Formula	● Nutro Natural Choice® Lite
● Merrick Senior Medley	● Pedigree Weight Maintenance™
● Natural Balance® Original Ultra™ R.C.	● Purina Beneful® Healthy Weight
● Formula for Dogs	● Purina® ONE® Healthy Weight
● Eukanuba® Weight Control	● Formula 3,343

⁷ Laflamme, D. 1998. Early Recognition and Management of Obesity. Vet Forum. March. p 47-56.

Each food has a different caloric density (Kcal/Kg) and should be fed the appropriate amount for the pet – sometimes the manufacturer’s guidelines provide more calories that required for the pet’s size.

Fruitables® is a vegetable-based high fiber dietary supplement. It is fortified with selected nutrients that have been shown in peer-reviewed scientific studies to promote healthy weight loss and provide the nutrients necessary to support heart and bone metabolic body functions and improve fat utilization. While many other nutrients have been promoted to be weight loss aids for dogs, only those in which there is scientific data to support this concept have been included in Fruitables®. In this way, one can be assured that the product is naturally derived and not overly fortified with unproven ingredients and marketing hype. Please note, however that Fruitables® is a dietary supplement. As such it must be labeled for “intermittent feeding only.”

While Fruitables® has been clinically tested for dogs; it is also effective in cats as well. Fruitables® may replace the corresponding amount of food fed on a daily basis according to the recommended feeding amounts as follows (Fruitables works with both dry and canned foods):

<u>Dogs</u>	<u>Cats</u>
Weight Loss	Maintenance & Digestive Support
Food – Replace up to 30% of food fed daily with Fruitables® (for example, ~1 cup of food is replaced with 2/3 cup of food, 1/3 cup of Fruitables®);	Up to 10 pounds: 1-3 <u>level</u> teaspoons* daily Over 10 pounds: Up to 5 <u>level</u> teaspoons* daily
Maintenance & Digestive Support	* Measuring teaspoons
Replace 10% of daily food fed with Fruitables®	

Upon reaching target weight, the amount of Fruitables® Pumpkin SuperBlend™ Weight Loss or Digestive Supplement should be reduced to 10% replacement of food fed as part of an ongoing weight maintenance program. Fruitables® Pumpkin SuperBlend™ Supplements will keep fresh in the refrigerator up to seven (7) days after opening, and can be frozen to extend the freshness longer.

Other active nutrients:

Oatmeal

Oatmeal is a super food in its own right, providing soluble and insoluble fiber to the SuperBlend™ formula, protein and very low levels of glutens. Oatmeal is known for providing essential trace nutrients as well, and is highly digestible and bioavailability.

Inulin

Inulin (commonly known as chicory root), is a pre-biotic source of fiber in our SuperBlend™ formula, working with the fiber in the Pumpkin and Oatmeal to provide a low calorie, high satiety means to ensure the pet is consuming an appropriate level of calories to achieve desired target weight.

Tomato & Blueberry Pomace

Pomaces, or the fiber remaining from processing of fruits & vegetables are included as a source of fiber and antioxidants. Recent research suggests that a blend of antioxidants may be more effective in supporting the immune system in responding to the stress of weight loss than a single source antioxidant.

Cinnamon

Cinnamon is known for its aroma and taste enhancing properties, and increasingly as a positive impact on metabolic function and regulator of blood sugar levels.

B-Vitamin Supplement

Our B-Vitamin supplement includes Calcium Pantothenate (B5), Pyroxidine Hydrochloride (B6), Folic Acid (B9), and Vitamin B12. B-Vitamin is essential in supporting cellular metabolism of proteins and fats, immune function, and providing nutrients for the G.I. tract microflora. Another key benefit for dogs is when metabolized with Methionine present in complete and balanced dog food; Taurine is created in the process.

Weight Loss Research

Our weight loss trial included seven obese beagles (3 control, 4 treatment) over a six week duration. All pets were fed the same diet, with the treatment group receiving Fruitables® Pumpkin SuperBlend™ Weight Loss supplement substituted for approximately 30% of the food, resulting in the same volume of food with fewer calories fed in the treatment diet than control diet. The results included significantly more weight loss in supplement group than control group, with an average loss of 1.5-2.0% of body weight per week. No negative impact on blood chemistry was indicated, and the treatment group showed evidence of more fat mobilization, or conversion into lean body mass.

Satiety Research

In a related study, 26 beagles were broken into two groups, fed at 3 hour intervals. One group was fed Fruitables® Pumpkin Digestive Supplement plus commercial weight loss diet and the other group was fed commercial weight loss diet only. The results were that the supplement group consumed less food and were provided fewer calories with better satiety than the higher caloric intake of the control diet alone.

Conclusion

Pet obesity is a critical health concern for up to 40% of pets today. In addition to concerns about quality of life, mobility and longevity, there is a significant cost in dollar and emotional terms for care and enjoyment of the special bond between the pet and owner. Fruitables® has discovered and harnessed the potential of vegetable fiber supplementation, notably pumpkin in the Fruitables® Pumpkin SuperBlend™ Weight Loss Supplement. Through our research and development, we've created a clinically proven, patent pending system of feeding that helps a pet safely lose up to 2% of their body weight per week, and maintain it when the target weight is reached. The pet also enjoys improved satiety (feeling of fullness when the Fruitables® feeding regimen is followed. Our approach makes the most difficult barrier to success – compliance, a problem of the past, and helps pets and pet parents to achieve our brand promise to love life together®.

In addition to Fruitables® Pumpkin SuperBlend™ Weight Loss Supplement, we also produce Fruitables® Pumpkin SuperBlend™ Digestive Supplement and Fruitables® Deliciously Healthy Dog Treats. The Digestive Supplement is formulated to help pets with digestive issues including constipation, diarrhea, nausea, and the effects of food transitions. It is also an excellent supplement for raw food diets. The Dog Treats feature Pumpkin or Sweet Potatoes as the #1 ingredient, deliver an amazing aroma and irresistible taste, with less than 9 calories each.



Biography



John E. Bauer, Ph.D., D.V.M., Dipl.ACVN is Professor of Small Animal Medicine and Surgery and holder of the Mark L. Morris Professorship of Clinical Nutrition in the College of Veterinary Medicine at Texas A&M University. He is the past chair and a current member of the Intercollegiate Graduate Faculty of Nutrition at Texas A&M. Bauer's areas of specialization are lipid biochemistry, disorders of lipid metabolism, and comparative biomedicine and nutrition. His studies have included lipoprotein and fatty acid metabolism of domestic and exotic animals as well as animal models of hypercholesterolemia and atherogenesis of humans.

He has written over 230 peer-reviewed and other publications, is the recipient of numerous grants, awards and honors and is listed in American Men and Women of Science, Who's Who in Veterinary Science and Medicine. He has received several Outstanding Paper Presentation Awards from the American Oil Chemists' Society, and C. E. Cornelius Young Investigator Research Award from the University of Florida. Bauer has chaired and has been an active member on several committees in the animal nutrition field over the past twenty years. Bauer lectures frequently on companion animal nutrition and lipid metabolism at veterinary scientific conferences and pet animal nutrition meetings.

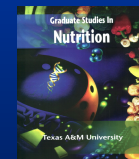
An active member on numerous committees, Bauer was appointed to the Committee on Nutrient Requirements of Dogs and Cats for the National Academy of Sciences, National Research Council, which recently published the "Nutritional Requirements of Dogs and Cats" as well as "your Dog's Nutritional Needs: A Science-Based Guide for Pet Owners".

Dr. Bauer received his B.S. in Chemistry with High Distinction from the University of Kentucky. His D.V.M. as well as his M.S. and Ph.D. in nutritional sciences are from the University of Illinois. He is a charter Diplomate of the American College of Veterinary Nutrition; an American Veterinary Medical Association recognized specialty organization.

Post-Feeding Satiety and Weight Loss of Dogs Fed a Vegetable-Based Fiber Supplement.

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Introduction

- Obesity is a growing epidemic in both human and companion animal nutrition.
- Dietary insoluble fiber is believed to support weight loss by increasing satiety and the mass of the food consumed without adding calories.

Experimental Animals and Diets

- Two diets were prepared differing in fiber content.
- Purina ONE[®] healthy weight formula (ONE) was compared to a diet consisting of ONE plus a vegetable-based fiber supplement (FS, Fruitables[®], Vet Science, LLC); crude fiber contents were 2.6% (ONE) vs 5.4% (FS), dry matter.

Diet Table

	Control (ONE)	Treatment (ONE + FS)
	g/100g DM	
Protein (Combustion)	29.6	28.2
Crude Fiber	2.6	5.4
Crude Fat	11.0	9.9
Ash	7.0	7.0
Carbohydrates (Calculated)	49.8	51.0
Calories (Calculated), Kcal/100g	371.0	357.5

Study Design

- Two studies were conducted
- 1. To evaluate satiety**
 - Diets were fed for 15 min each at
 - 8am and 3pm (7h interval)
 - 8am and 11am (3h interval)
 - Fourteen female adult Beagles for 7h interval and 12 female adult Beagles for 3h interval were randomly divided into 2 diet groups.
 - Amounts offered at each feeding were 1.2 times metabolic energy requirement (MER, $125 \times BW^{0.75}$) for 3 consecutive days in 7h interval and 2 consecutive days in 3h interval.
 - A cross-over design was used.

To evaluate the weight loss effect for 6 weeks of dietary restriction period

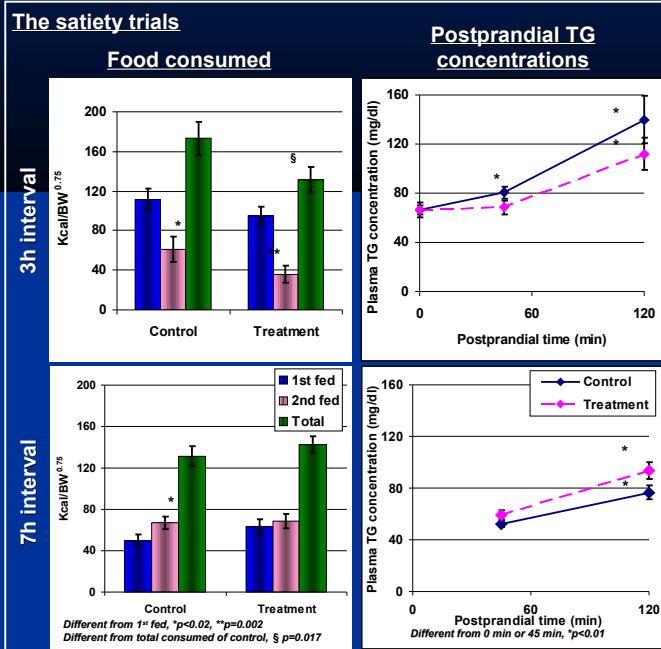
- Seven obese Beagles were selected and divided into 2 groups. (3 dogs for the control diet, and 4 dogs for the treatment diet)
- The diets were fed once daily (ca. 60% of obese MER) for 1 hour for 42 days.

Experimental Design

	The satiety trials		The weight loss trial (Initial)
	3h interval	7h interval	
Total sample size	12	14	7
BW, kg	13.0 ± 1.0	13.8 ± 0.9	15.2 ± 1.0
BF, %	36.3 ± 2.2	38.4 ± 1.9	45.1 ± 1.6
Feeding time	8AM, 11AM	8AM, 3PM	9AM
Feeding amount	1.2×MER	1.2×MER	0.6×MER

Objective

- The objective of the study was to measure satiety and weight loss in Beagles fed a vegetable-based fiber supplement.



Materials and Methods

- The satiety trials**
 - Blood samples were collected (45min and 120min postprandially)
 - Plasma triglyceride (TG) was measured by enzymatic colorimetric assay.
 - Food intakes were measured after each feeding.
 - Body weight (BW) and body fat (BF) by bioelectrical impedance were determined prior to the study of each satiety measurement period.
 - Water was offered ad libitum.
 - Dogs were allowed to exercise freely.
- The 6 weeks weight loss trial**
 - Post prandial blood samples were collected at 60min (days 1, 28, and 42) for TG determination.
 - At the same days of the blood sample collection, BF was recorded.
 - Food intakes and BW were recorded daily and weekly.
- Repeated measures ANOVA (Statistix 8 or SPSS) was performed under $\alpha=0.05$ for food consumed of the satiety trials and for the weight loss trial.
- Where there was a significance, paired t test or one-way AOV/Kruskal-Wallis test after checking the normality by Shapiro-Wilks test was conducted.
- Tukey test was used for post Hoc multiple comparisons.
- Wilcoxon Signed Rank test or paired t test depending on the normality was conducted for the total calorie consumed in the satiety trials.

Summary

- The Satiety trials**
 - Both the 3h and 7h interval food intakes were not different from the control group.
 - However, significantly fewer total calories were consumed with the FS diet during the 3h interval ($p=0.017$).
 - Plasma TG concentration was significantly increased at 120 min post feeding independent of diet ($p<0.01$).
 - FS did not affect TG concentrations.
- The 6 weeks weight loss trial**
 - The FS group significantly reduced % BW change ($p=0.002$, one-way AOV) and % BF change ($p=0.008$, one-way AOV) over time.
 - Diet did not affect TG concentrations.

Conclusion

- FS provided fewer calories with the same degree of satiety as the higher calorie intake of the control diet.
- FS may improve fullness at lower calorie intake during weight loss with no effect on hypertriglyceridemia.

Future Plan

- Peptide YY is secreted from the distal small intestine and the large intestine after food consumed by increasing satiety.
- Therefore, the plasma Peptide YY concentration will be assessed for the satiety effect in both satiety and weight loss trials.