

SMART BALANCE®

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Coronary heart disease (CHD) continues to be a major cause of mortality globally. Among the risk factors that can be modified are dietary habits of an individual. In this context, reduction of excess consumption of dietary fat and especially saturated fatty acids has been advocated as a tool to reduce CHD risk. Depending on the type and amount of fat consumed, blood total (TC) and low-density lipoprotein cholesterol (LDL-C) may be adversely modulated. In line with this reasoning, a number of expert panels have drawn various recommendations aimed at reducing blood lipid associated CHD risk factors.

The FAO/WHO Expert Committee on Oil and Fats for Human Nutrition (1993) has recommended optimum fat intake at 30% of our daily calorie intake. The American Heart Association (AHA) has taken a similar stand advocating a 30% fat energy diet, but it further refined its recommendation so that the

saturated, monounsaturated and polyunsaturated fatty acids are equally distributed. This means that each fatty acid class should provide 10% of our daily energy requirement. A number of clinical studies have tested this recommended AHA step-1 diet and found that it was suitable to modulate blood cholesterol levels in the population. This was the basis on which PORIM set about to develop an AHA-type formulation that maximized the content of palm olein in the product.

PRODUCT DEVELOPMENT

None of the natural oils and fats available commercially is able to meet the AHA specification on their own. These oils are typically high in polyunsaturated, monounsaturated or saturated fatty acids. It was obvious that a blend of different edible oils was required. From PORIM's viewpoint, such a blend should maximize the content of palm olein and yet meet the AHA specification. This requirement was met and the following international patents presently cover the product:

Smart Balance® is the registered trademark of GFA (Great Foods of America) Brands Incorporated and developed through a master licensing agreement between GFA Brands Inc., Brandeis University, Waltham, MA, United States and PORIM, Malaysia.

GFA Brands Inc. is keen to franchise Smart Balance® to Malaysian and other entrepreneurs through a sub-licensing agreement.

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- US5578334 – K. Sundram, D. Perlman and K.C. Hayes. Increasing the HDL level and the HDL/ LDL ratio in human serum with fat blends
- US5874117 – K. Sundram, D. Perlman and K.C. Hayes. Blends of palm fat and corn oil provide oxidation-resistant shortenings for baking and frying

- US 08/626461 – K. Sundram, D. Perlman and K.C. Hayes. Increasing the HDL level and the HDL/ LDL ratio in human serum by balancing saturated and polyunsaturated fatty acids

Several variations of the formulation are now available as different food products.

MARGARINE AND BUTTER USERS...

Your total cholesterol is not the full story...
You should also know your HDL "good"
& LDL "bad" cholesterol.



*BALANCING YOUR FATS MAY HELP YOU— IMPROVE YOUR CHOLESTEROL RATIO

The basic premise of the Smart Balance® program and foods is to provide the optimum proportion of polyunsaturates, monounsaturates and saturates in a heart healthy diet. We believe that such a diet will help improve the good to bad cholesterol ratio (HDL/LDL). Total fat must be limited to 30% of

calories and dietary cholesterol to under 300mg per day. Also avoid trans fatty acids. Naturally, exercise can help. (Diet is based on the American Heart Association Step 1 Diet).

SMART BALANCE BUTTERY SPREADS:

No Hydrogenated Oil –
No Trans Fatty Acids with
the Taste & Texture of Butter –
Superb for Cooking & Baking.

SMART BALANCE CREAMY CHEDDAR - FLAVOR SLICES:

Now cheese has an
improved balance of
fats with low cholesterol
and reduced fat.



*U.S. Patents 5,578,334 & 5,843,497

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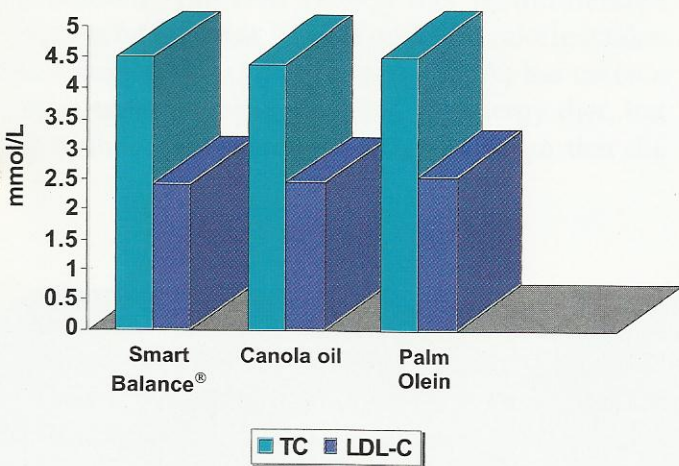
HEALTH BENEFITS OF SMART BALANCE®

The ability of Smart Balance® to regulate blood cholesterol levels was evaluated in a randomized human dietary trial. Healthy volunteers were fed carefully designed whole food diets enriched by Canola oil, palm olein or Smart Balance®. Volunteers received each diet at 31% energy as fat and <200 mg/cholesterol/day over three consecutive 4-week periods. This experimental design therefore compared the exchange of saturated palmitic acid from palm olein with either linoleic acid or oleic acid from Smart Balance® and Canola oil respectively.

One of the striking features of this dietary study was the constant serum total (TC) and low-density lipoprotein (LDL-C) cholesterol values across the three dietary manipulations (Figure 1). The results therefore imply that in normal healthy individuals who typically consume a low-fat diet (<30% fat energy), it is unlikely that moderate exchanges among the saturated, polyunsaturated or monounsaturated fatty acids will result in appreciable effects on serum TC and LDL-C.

Figure 1

Effect of Smart Balance® on Serum TC and LDL-C (mmol/L)



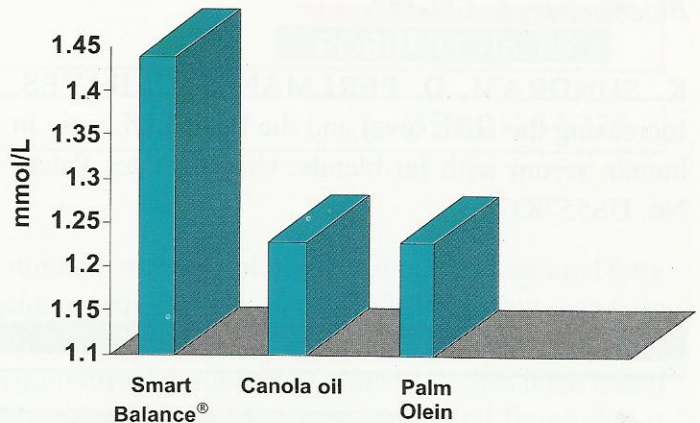
IMPACT OF SMART BALANCE® ON BENEFICIAL HDL-C

Feeding Smart Balance® to healthy volunteers with normal blood cholesterol levels resulted in a significant elevation of beneficial HDL-C compared to the palm olein or Canola-rich diets. This was equivalent to a hefty 17% increase in the beneficial HDL-C (Figure 2). As a result of the modulations in the various lipoproteins,

Smart Balance® resulted in a beneficial reduction (14%) in the LDL/HDL-C ratio compared to the other two diets tested (Figure 3).

Figure 2

Smart Balance® Beneficially Increases HDL-C



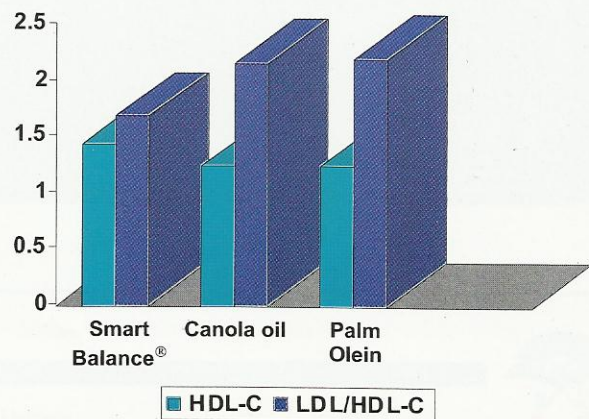
PATENTED BENEFITS CLAIMED BY SMART BALANCE®

Smart Balance® is a unique combination of fatty acids required for human metabolism and which modulate human lipoproteins beneficially. The net result is a reduction in blood lipid associated coronary heart disease risk factors, namely, TC and LDL-C, while beneficially increasing the protective HDL-C. These benefits of Smart Balance® are presently the subject of three different United States Patents.

In addition, the fatty acid composition of Smart Balance® duplicates the recommendations of the American Heart Association (AHA) Step-1 diet while incorporating maximum palm olein in its formulation. The versatility of the blend has been demonstrated in various product formulations including salad and cooking oils and margarine.

Figure 3

Smart Balance® Beneficially Increases HDL-C and Reduces LDL/HDL-C ratio



REFERENCES

K. SUNDRAM, K.C. HAYES, O.H. SIRU. (1995) Both dietary 18:2 and 16:0 may be required to improve the serum LDL/HDL cholesterol ratio in normocholesterolemic men. *J. Nutritional Biochemistry* 6: 179-187.

K. SUNDRAM, D. PERLMAN, K.C. HAYES. Increasing the HDL level and the HDL/LDL ratio in human serum with fat blends. United States Patent No. US5578334.

K. SUNDRAM, D. PERLMAN, K.C. HAYES. Blends of palm fat and corn oil provide oxidation-resistant shortening for baking and frying. United States Patent No. US5874117.

K. SUNDRAM, D. PERLMAN, K.C. HAYES. Increasing the HDL level and the HDL/LDL ratio in human serum by balancing saturated and polyunsaturated fatty acids. United States Patent No. US 08/626461.

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