Clinical Study of the Effects of Exposure of Various SALATRIM Preparations to Subjects in a Free-Living Environment

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Three different members of the SALATRIM family of triacylglycerols have been tested in a 42-day clinical study with free living subjects. The study included a 1-week pre-exposure period, a 4-week exposure period, and a 1-week post-exposure period. In the pre- and post-exposure periods, all subjects received 60 g/day of control fat (partially hydrogenated soy oil). During the exposure period, three groups of subjects were fed different levels (30, 45, or 60 g/day) of SALATRIM prepared through interesterification of triacetin, with hydrogenated soy (SALATRIM 23SO); one group was fed 60 g/day of SALATRIM prepared with tripropionin, tributyrin, and hydrogenated soy (43SO); and one group was fed SALATRIM prepared with tributyrin acid and hydrogenated soy (4SO); two control groups were fed control fat for the entire duration of the study. Increases in AST and ALT observed in the 60 g/day SALATRIM groups were larger than that observed in the control groups; however, the mean values remained well within the normal ranges. After the initial increase, the ALT and AST levels decreased, approaching the levels observed at the beginning of the exposure period. The changes in AST and ALT appeared to be associated with the high-fat diet, since excursions were noted for both the control and SALATRIM groups. Some subjects reported increased levels of gastrointestinal discomfort. These complaints were observed more frequently in the high-dose SALATRIM group. This study also shows that ingestion of SALATRIM will not produce any clinically important effects at the anticipated use level.

INTRODUCTION

SALATRIM is a family of reduced-calorie triacylglycerols prepared by the interesterification of triglycerides containing long-chain saturated fatty acids with short-chain fatty acid triacylglycerols. The interesterification process results in mixtures of triacylglycerols that contain both long-chain saturated fatty acids and short-chain fatty acids. When the long-chain fatty acid source is predominantly stearic acid, SALATRIM preparations range in caloric availability from 4.5 to 5.5 kcal/g compared to the usual 9 kcal/g for normal vegetable oils (Finley et al., 1994a). Through selection of the short-chain fatty acids and control of the proportion of short- to long-chain fatty acids the properties of SALATRIM preparations can be varied from a cocoa butter substitute, to a shortening, to a fat suitable for filled milk and other dairy products.

Previously we reported on the effects of SALATRIM in studies in which human subjects were confined to a clinic. The subjects were exposed to SALATRIM at levels as high as 60 g/day for times ranging from 1 to 7 days. In those studies a slight increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) activities were observed. In this study, three members of the SALATRIM family were fed at levels up to 60 g/day for 28 days, during which time the subjects were free-living. During the course of the study the subjects kept complete dietary records, which also included any changes in their perceived health status. On a weekly basis, body weight was recorded and blood was drawn for serum chemistry analysis. The goals of the study were to determine whether the health status of the subjects was affected by prolonged consumption of high levels of SALATRIM and to further explore the previously observed increases in serum transaminase levels.

METHODS AND MATERIALS

Test Oils. SALATRIM test materials were prepared as described by Klemann et al. (1993). The materials were then vacuum distilled to control of the distribution of short- to long-chain fatty acids in the final preparations, thus improving the functional quality of the oils and the sensory qualities of delivery vehicles. SALATRIM 23SO was prepared by the interesterification of triacetin and tripropionin with hydrogenated soy oil at a ratio of 2.3:0.28:1.0. SALATRIM 43SO was prepared by the interesterification of tributyrin and tripropionin with hydrogenated soy oil at a ratio of 2:0.18:1. SALATRIM 4SO was prepared by the interesterification of tributyrin with hydrogenated soy oil at a ratio of 12:1. The SALATRIM preparations were then refined by deodorization. The deodorized oils were distilled in a two-stage falling wiped film still (Pope Scientific Co, Menomonee Falls, WI). Each section of the still had 1 ft^2 of evaporating surface. The second stage of the evaporator was equipped with a diffusion pump. The first-stage pressure was 900 μm and the second stage was 45 μm. Distillation temperature for the first stage ranged from 200 to 201 °F, and the second stage temperature was 175–185 °F. The products of distillation were then deodorized and incorporated into food products as described below.

The three preparations were analyzed for glyceride distribution according to a modification of the IUPAC standard method 2.323 (IUPAC, 1985). The acyl carbon number profile (ACN) and acylglycerol contents of the SALATRIM were determined by modifications of this procedure as reported by Huang et al. (1994a).

Control oil for the study was partially hydrogenated soy oil (SHO-2, Perdue Inc., Salisbury, MD). The SALATRIM preparations and control soy oil were incorporated into various food products such that each vehicle would deliver 15 g of SALATRIM or soy oil at a single eating occasion.

Delivery Vehicles. Ice cream, chocolate milk, pudding, and yogurt were produced in the Cornell University Dairy by conventional processes. Formulations for the dairy-based products were adjusted so that each individually packaged serving would deliver 15 g of control oil or SALATRIM in each unit. With the exception of slightly higher than normal fat contents (4.9% fat in chocolate milk and 7.9% fat in yogurt), all formulations were simple substitutions for milk fat. Chocolate milk was prepared in multiple batches every 2 weeks as needed. All other products were produced in a single lot prior to the initiation of the study. Ingredients other than SALATRIM were supplied by the Cornell University Dairy.

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Table 1. Acylglycerols of SALATRIM Test Materials

acylglycerol identification	mean[a] (%)	SD	CV (%)
Acylglycerol Components of SALATRIM 23SO			
diacetylstearoylglycerol	65.27	0.294	0.45
acetylpropionylglycerol	12.45	0.063	0.51
acetylstearoylglycerol	7.56	0.678	8.97
diacetylpalmitoylglycerol	7.10	0.077	1.08
acetylpropionylglycerol	1.62	0.018	1.09
distearoylacetylglycerol	1.58	0.023	1.46
acetylpalmitoylglycerol	1.30	0.020	1.51
acetylpalmitoylstearoylglycerol	1.07	0.165	15.44
diacetylarachidoylglycerol[b]	0.90	0.018	1.99
dipropionylstearoylglycerol[b]			
acetylpropionylarachidoylglycerol	0.64	0.015	2.35
diacetylbehenoylglycerol	0.59	0.021	3.58
dipalmitoylacetylglycerol	0.34	0.081	24.12
stearoylglycerol	<0.02	ND[c]	ND
summary			
monoacylglycerols	<0.02	ND	ND
diacylglycerols	8.85	0.681	7.69
triacylglycerols	91.56	0.456	0.50
total	100.42	0.720	0.72
Acylglycerol Components of SALATRIM 43SO			
dibutyrylstearoylglycerol	52.09	0.299	0.57
distearoylbutyrylglycerol	11.99	0.046	0.38
propionylbutyrylstearoylglycerol	8.10	0.047	0.58
dibutyrylpalmitoylglycerol	7.05	0.053	0.75
butyrylstearoylglycerol	5.05	0.060	1.18
butyrylpalmitoylstearoylglycerol	4.40	0.040	0.92
propionylbutyrylpalmitoylglycerol	1.24	0.008	0.61
distearoylpropionylglycerol	1.08	0.008	0.73
butyrylpalmitoylglycerol	0.97	0.011	1.13
tristearin	0.89	0.076	8.56
dipropionylstearoylglycerol	0.84	0.012	1.43
propionylpalmitoylstearoylglycerol	0.81	0.008	1.04
propionylstearoylglycerol	0.80	0.009	1.15
dibutyrylarachidoylglycerol	0.75	0.028	3.70
distearoylpalmitoylglycerol	0.75	0.048	6.45
triacylglycerol ACN = 41	0.69	0.054	7.80
dibutyrylbehenoylglycerol	0.61	0.033	5.40
dipalmitoylbutyrylglycerol	0.52	0.011	2.18
triacylglycerol ACN = 25	0.40	0.424	105.79
stearoylglycerol	0.26	0.085	32.49
triacylglycerol ACN = 22	0.24	0.009	3.75
triacylglycerol ACN = 29	0.20	0.179	89.38
summary			
monoacylglycerols	0.26	0.085	32.49
diacylglycerols	6.82	0.069	1.02
triacylglycerols	92.68	0.416	0.45
total	99.75	0.460	0.46
Acylglycerol Components of SALATRIM 4SO			
butyrylpalmitoylglycerol	0.59	0.020	3.39
triacylglycerol ACN = 21	0.32	0.015	4.60
dinutylmyristoylglycerol	0.78	0.077	9.82
butyrylstearoylglycerol	1.73	0.047	2.72
dibutyrylpalmitoylglycerol	10.08	0.156	1.55
dibutyrylmarjaroylglycerol	0.47	0.160	34.24
dibutyrylstearoylglycerol	84.21	0.622	0.74
dibutyrylarachidoylglycerol	0.86	0.022	2.56
dibutyrylbehenoylglycerol	1.01	0.050	4.91
butyrylpalmitoylstearoylglycerol	0.78	0.024	3.02
butyryldistearoylglycerol	1.04	0.291	28.07
summary			
monoacylglycerols	ND	ND	ND
diacylglycerols	2.32	0.046	1.97
triacylglycerols	99.55	0.903	0.91
total	101.87	0.919	0.90

[a] Mean of 13 determinations. [b] Unresolved peaks. [c] ND, not detected.

Cinnamon raisin muffins, chocolate cake, lemon cake, and waffles were prepared at the Swanson Co., Omaha, NE, prior to the study and held frozen until they were dispensed to the subjects. The formulations of the baked products were adjusted so that each individual portion delivered 15 g of control oil or SALATRIM per serving. Muffins and cakes were one cupcake size per serving, and waffles were two waffles per serving. Control oil and SALATRIM substitutions were 100% replacement for

Table 2. Mean Clinical Chemistry Values Observed within Each Group

factor	group[a]	screening	day 1	day 8	day 15	day 22	day 29	day 36	day 43
alanine aminotransferase	control 1	19.72 ± 7.06	19.48 ± 6.10	20.12 ± 7.77	21.16 ± 7.78	22.60 ± 10.34[b]	22.80 ± 9.63[b]	23.40 ± 11.60[b]	21.68 ± 7.84
normal range 0–49	control 2	21.13 ± 7.83	24.50 ± 10.05	24.96 ± 14.62	28.71 ± 20.77[b]	28.21 ± 21.63	30.46 ± 19.87[b]	27.96 ± 18.03[b]	27.33 ± 16.15
milliunits/mL	C. control	20.41 ± 7.40	21.94 ± 8.57	22.49 ± 11.77	24.86 ± 15.86[b]	25.35 ± 16.90[b]	26.55 ± 15.83[b]	25.63 ± 15.11[b]	22.45 ± 12.80[b]
	23SO-30	19.91 ± 7.53	22.65 ± 7.57	22.87 ± 8.70	28.09 ± 19.47[b]	24.22 ± 9.26	25.78 ± 11.20	24.70 ± 8.54	22.04 ± 7.29
	23SO-45	19.45 ± 7.42	20.95 ± 8.33	21.14 ± 7.78	24.73 ± 7.69[b]	24.05 ± 7.48[b]	25.18 ± 9.37[b]	24.91 ± 10.44[b]	24.18 ± 9.82
	23SO-60	18.13 ± 3.90	20.91 ± 6.03	21.30 ± 6.68	28.70 ± 9.96[b]	27.61 ± 9.26[b]	28.22 ± 11.01[b]	25.74 ± 8.77[b]	21.40 ± 4.91
	43SO-60	20.46 ± 8.80	21.23 ± 9.03	21.31 ± 8.55	33.69 ± 22.71[b]	30.77 ± 17.71[b]	31.38 ± 19.68[b]	29.54 ± 15.26[b]	25.69 ± 11.88
	4SO-60	18.58 ± 6.79	26.53 ± 21.31	25.00 ± 15.55	33.16 ± 23.61[b]	33.95 ± 19.35[b]	27.26 ± 14.56	27.53 ± 15.53	23.37 ± 14.15
asparate aminotransferase	control 1	19.92 ± 4.52	19.72 ± 3.51	20.44 ± 4.07	20.92 ± 3.85	21.36 ± 4.90	21.56 ± 4.98	22.08 ± 6.32	21.24 ± 4.29
normal range 4–36	control 2	19.96 ± 5.92	21.38 ± 5.15	22.00 ± 7.92	24.08 ± 14.23	24.17 ± 10.76[b]	25.67 ± 10.20[b]	22.71 ± 9.56	23.29 ± 8.13
milliunits/mL	C. control	19.94 ± 5.19	20.53 ± 4.42	21.20 ± 6.24	22.47 ± 10.34	22.73 ± 8.33[b]	23.57 ± 8.15[b]	22.39 ± 7.99	22.24 ± 6.48[b]
	23SO-30	18.35 ± 4.00	21.04 ± 5.53	20.30 ± 6.24	23.52 ± 14.03[b]	21.87 ± 5.75	22.04 ± 6.59[b]	21.22 ± 5.36	20.39 ± 5.39
	23SO-45	19.14 ± 4.82	19.23 ± 5.07	19.91 ± 6.16	22.18 ± 6.62[b]	22.50 ± 5.73[b]	23.00 ± 6.95[b]	23.64 ± 7.72[b]	22.00 ± 6.75
	23SO-60	17.17 ± 2.89	20.17 ± 7.29	20.48 ± 6.87	23.83 ± 5.51	23.04 ± 5.45[b]	22.74 ± 4.68[b]	21.61 ± 5.47	19.30 ± 3.65
	43SO-60	19.85 ± 6.34	19.54 ± 5.33	20.77 ± 6.22	28.31 ± 11.40[b]	26.08 ± 8.93[b]	24.77 ± 8.62[b]	27.46 ± 18.70	21.54 ± 6.55
	4SO-60	17.53 ± 5.11	21.95 ± 15.01	21.26 ± 9.57	25.68 ± 16.76	27.47 ± 13.40[b]	22.79 ± 10.74	21.89 ± 7.69	20.00 ± 8.20
alkaline phosphatase	control 1	69.52 ± 16.49	68.20 ± 15.73	69.72 ± 16.42	68.92 ± 14.82	70.84 ± 15.67	70.60 ± 15.89	75.52 ± 16.59[b]	74.28 ± 16.40
normal range M =	control 2	75.88 ± 13.54	74.83 ± 14.88	77.29 ± 15.95	76.79 ± 15.21	78.75 ± 15.33	79.00 ± 16.55	82.29 ± 14.20[b]	78.92 ± 14.41
52–113 milliunits/mL,	C. control	72.63 ± 15.30	71.45 ± 15.52	73.43 ± 1647	72.78 ± 15.38	74.71 ± 15.85	74.71 ± 16.60	78.84 ± 15.68[b]	76.55 ± 15.47[b]
F = 44–114	23SO-30	77.04 ± 17.75	77.39 ± 19.07	77.35 ± 19.63	75.17 ± 19.64[b]	74.35 ± 21.96	73.78 ± 20.20[b]	77.35 ± 21.16	77.35 ± 19.88
milliunits/mL	23SO-45	77.05 ± 18.21	76.00 ± 17.14	76.36 ± 16.54	75.45 ± 19.11	74.05 ± 16.99	71.27 ± 15.08[b]	77.91 ± 16.50	78.14 ± 16.99
	23SO-60	68.26 ± 16.09	66.04 ± 16.73[b]	70.09 ± 16.75	69.17 ± 15.51	64.83 ± 14.78[b]	65.83 ± 15.94[b]	69.61 ± 15.71	67.17 ± 13.32
	43SO-60	84.46 ± 17.47	78.46 ± 16.72	79.69 ± 15.92	82.92 ± 24.08	76.54 ± 20.12	76.08 ± 18.79	79.85 ± 19.81	81.46 ± 20.14
	4SO-60	73.21 ± 15.62	74.79 ± 20.03	77.32 ± 17.47	74.05 ± 14.71[b]	72.05 ± 15.71[b]	71.58 ± 16.06[b]	74.89 ± 17.35	72.16 ± 19.91

factor	group[a]	screening	day 1	day 8	day 15	day 22	day 29	day 36	day 43
γ-glutamyltransferase	control 1	15.60 ± 4.30	14.40 ± 4.29[b]	15.08 ± 4.53	15.04 ± 4.62	16.00 ± 4.77[b]	15.48 ± 4.72	15.92 ± 4.96[b]	15.76 ± 5.58
normal range 6–43 m	control 2	17.29 ± 6.50	18.21 ± 8.03	18.79 ± 8.69	19.58 ± 10.93	20.63 ± 13.63	21.96 ± 18.46	22.38 ± 18.00[b]	21.79 ± 16.49
illiunits/mL	C. control	16.43 ± 5.50	16.27 ± 6.62[b]	16.90 ± 7.07	17.27 ± 8.55	18.27 ± 10.29[b]	18.65 ± 13.61	19.08 ± 13.35[b]	18.71 ± 12.45[b]
	23SO-30	17.52 ± 6.33	18.35 ± 6.81	18.91 ± 6.87	19.91 ± 7.54	19.87 ± 8.08	19.26 ± 7.74	20.30 ± 7.56	18.91 ± 6.69
	23SO-45	19.73 ± 9.65	19.23 ± 7.87	19.05 ± 6.83	18.68 ± 7.27	19.50 ± 8.09	17.45 ± 6.93[b]	18.77 ± 7.84	18.36 ± 8.13
	23SO-60	14.65 ± 5.98	14.65 ± 6.61	15.30 ± 6.23	15.61 ± 6.67	15.26 ± 6.18	15.91 ± 6.84	15.96 ± 7.09	15.39 ± 7.09
	43SO-60	17.69 ± 7.65	17.62 ± 8.34	18.46 ± 7.46	20.23 ± 17.17	19.15 ± 14.80	19.54 ± 14.68	19.38 ± 14.30	19.92 ± 13.67
	4SO-60	18.47 ± 8.02	21.53 ± 11.73	21.84 ± 11.43	22.00 ± 13.27	21.63 ± 12.33	20.47 ± 13.47	21.79 ± 13.57	20.74 ± 15.11
creatinine normal range	control 1	1.10 ± 0.15	1.09 ± 0.15[b]	1.12 ± 0.16	1.13 ± 0.14	1.15 ± 0.14[b]	1.14 ± 0.15	1.12 ± 0.16	1.14 ± 0.14
0.6–1.7 mg/dL	control 2	1.10 ± 0.18	1.10 ± 0.17[b]	1.14 ± 0.17	1.15 ± 0.19	1.17 ± 0.20[b]	1.15 ± 0.19	1.16 ± 0.19	1.15 ± 0.17
	C. control	1.11 ± 0.17	1.10 ± 0.16[b]	1.13 ± 0.16	1.14 ± 0.16	1.17 ± 0.17[b]	1.15 ± 0.17	1.14 ± 0.17	1.15 ± 0.16
	23SO-30	1.12 ± 0.17	1.11 ± 0.17	1.14 ± 0.15	1.12 ± 0.16	1.14 ± 0.16	1.15 ± 0.18	1.13 ± 0.17	1.14 ± 0.15
	23SO-4S	1.11 ± 0.18	1.10 ± 0.15[b]	1.15 ± 0.16	1.15 ± 0.16	1.15 ± 0.15	1.15 ± 0.17	1.15 ± 0.17	1.15 ± 0.17
	23SO-60	1.12 ± 0.17	1.11 ± 0.17[b]	1.14 ± 0.15	1.12 ± 0.16	1.14 ± 0.16	1.15 ± 0.18	1.13 ± 0.17	1.14 ± 0.15
	43SO-60	1.06 ± 0.14	1.05 ± 0.15[b]	1.12 ± 0.15	1.06 ± 0.16[b]	1.09 ± 0.15	1.08 ± 0.11	1.09 ± 0.13	1.08 ± 0.15
	4SO-60	1.09 ± 0.15	1.04 ± 0.15	1.08 ± 0.15	1.09 ± 0.14	1.11 ± 0.15	1.08 ± 0.14	1.10 ± 0.13	1.09 ± 0.13
uric acid normal	control 1	4.76 ± 1.37	4.42 ± 1.04	4.36 ± 1.00	4.45 ± 1.04	4.39 ± 1.03	4.64 ± 1.17[b]	4.53 ± 1.12	4.70 ± 0.99
range M = 2.2–9.1	control 2	4.21 ± 1.45	4.19 ± 1.34	4.14 ± 1.36	4.12 ± 1.29	4.27 ± 1.31	4.40 ± 1.32[b]	4.14 ± 1.22	4.35 ± 1.40
mg/dL, F = 2.0–6.0	C. control	4.53 ± 1.40	4.33 ± 1.19	4.27 ± 1.19	4.31 ± 1.16	4.36 ± 1.16	4.56 ± 1.23[b]	4.36 ± 1.17	4.55 ± 1.20[b]
mg/dL	23SO-30	4.78 ± 1.63	4.76 ± 1.68	4.65 ± 1.70	4.46 ± 1.56	4.63 ± 1.72	4.68 ± 1.45	4.72 ± 1.83	4.71 ± 1.55
	23SO-45	4.44 ± 1.44	4.24 ± 1.36	4.44 ± 1.65	4.12 ± 1.44[b]	4.13 ± 1.17	4.44 ± 1.27	4.16 ± 1.27	4.28 ± 1.23
	23SO-60	4.29 ± 0.98	4.11 ± 1.02	4.12 ± 0.92	4.06 ± 0.92	4.15 ± 0.97	4.22 ± 1.27	3.98 ± 1.09[b]	4.26 ± 1.17
	43SO-60	4.25 ± 0.94	4.22 ± 1.10[b]	4.55 ± 1.17	4.20 ± 1.18	4.12 ± 1.05[b]	4.31 ± 1.25	4.12 ± 0.91	4.15 ± 0.94
	4SO-60	4.72 ± 1.72	4.56 ± 1.50	4.51 ± 1.56	4.52 ± 1.45	4.29 ± 1.54	4.17 ± 1.39[b]	4.33 ± 4.52	4.48 ± 1.62
cholesterol normal	control 1	185.84 ± 31.66	179.24 ± 34.84	178.32 ± 33.95	182.56 ± 35.58	187.56 ± 36.95	182.68 ± 34.97	186.36 ± 37.00	185.92 ± 34.95
range 109–208	control 2	186.46 ± 35.30	182.04 ± 36.75[b]	175.13 ± 31.84	176.04 ± 35.20	181.29 ± 39.20	182.00 ± 34.35	183.21 ± 35.52[b]	178.17 ± 40.27
mg/dL	C. control	186.14 ± 33.14	180.61 ± 35.44	176.76 ± 32.63	179.37 ± 35.18	184.49 ± 37.80[b]	182.35 ± 34.31[b]	184.82 ± 35.94[b]	182.12 ± 37.46
	23SO-30	179.13 ± 30.94	181.26 ± 31.28	178.35 ± 32.27	181.48 ± 39.54	177.91 ± 30.61	180.70 ± 29.01	183.00 ± 27.63	179.83 ± 30.04
	23SO-45	180.64 ± 35.42	173.36 ± 36.01	169.82 ± 34.05	172.36 ± 38.39	171.50 ± 32.07	167.23 ± 33.73	170.50 ± 33.26	175.77 ± 34.76
	23SO-60	177.74 ± 36.77	181.00 ± 38.09	178.70 ± 36.97	172.22 ± 41.51[b]	172.83 ± 32.39	177.30 ± 36.74	180.13 ± 40.10	177.70 ± 38.98
	43SO-60	178.62 ± 20.53	175.77 ± 21.28	175.85 ± 26.41	161.00 ± 18.09[b]	161.77 ± 20.69	164.15 ± 21.20[b]	169.62 ± 21.03	174.69 ± 25.37
	4SO-60	183.72 ± 20.55	182.33 ± 25.31	182.06 ± 23.74	182.61 ± 25.80	176.06 ± 22.21	175.39 ± 24.45	177.56 ± 18.22	177.78 ± 21.35
calcium normal range	control 1	8.68 ± 0.20	9.25 ± 0.45	9.22 ± 0.39	9.02 ± 0.35[b]	9.26 ± 0.40	9.01 ± 0.35[b]	9.00 ± 0.40[b]	8.94 ± 0.39
8.5–11.1 mg/dL	control 2	8.97 ± 0.30	9.27 ± 0.42[b]	9.02 ± 0.29	9.05 ± 0.32	9.20 ± 0.29[b]	9.03 ± 0.43	8.96 ± 0.38	8.84 ± 0.28
	C. control	8.84 ± 0.29	9.26 ± 0.43	9.12 ± 0.36	9.03 ± 0.33[b]	9.22 ± 0.35[b]	9.02 ± 0.39	8.98 ± 0.39[b]	8.89 ± 0.34[b]
	23SO-30	8.97 ± 0.49	9.23 ± 0.49	9.19 ± 0.23	9.04 ± 0.35[b]	9.20 ± 0.28	9.02 ± 0.33[b]	9.05 ± 0.44	9.09 ± 0.39
	23SO-45	8.80[c]	9.07 ± 0.51	9.16 ± 0.38	9.04 ± 0.42	9.10 ± 0.38	8.87 ± 0.37[b]	9.07 ± 0.49	9.02 ± 0.40
	23SO-60	9.13 ± 0.35	9.37 ± 0.52[b]	9.14 ± 0.34	8.92 ± 0.35[b]	9.04 ± 0.34	9.07 ± 0.44	8.90 ± 0.43[b]	8.94 ± 0.39
	43SO-60	8.90[c]	9.23 ± 0.59	9.07 ± 0.34	8.76 ± 0.49[b]	9.13 ± 0.33	8.88 ± 0.45[b]	8.81 ± 0.44[b]	8.91 ± 0.32
	4SO-60	8.74 ± 0.26	9.30 ± 0.54	9.17 ± 0.33	9.11 ± 0.35	9.09 ± 0.38	8.96 ± 0.37	9.07 ± 0.53	8.97 ± 0.41

[a] Subjects per group: control 1, 25; control 2, 24; C. control, 49; 23SO-30, 23; 23SO-45, 22; 23SO-60, 23; 43SO-60, 13; 4SO-60, 19. [b] Significantly different from day 8 at $P < 0.05$. (Statistical tests reported for days 1–43 only for subjects completing the study.) [c] Insufficient data for calculating standard deviation.

formula fats. Ingredients were supplied by Swanson Co. except for SALATRIM.

Clinical Study. The clinical phase of the study was conducted at Harris Laboratories, Inc., in Lincoln, NE. The study protocol was reviewed and approved by the Harris Institutional Review Board. Subjects were healthy volunteers, males and females between 19 and 65 years of age, recruited from the local area. The following criteria were evaluated to determine volunteer health and eligibility: height and weight, complete medical and nutritional history, a physical examination, biochemical, hematological, and urological profiles, screening for drugs of abuse and, for females, a pregnancy test.

The experimental design was a randomized, double-blind, multiple-dose, parallel comparison of the fat replacement SALATRIM 23SO, 4SO, or 43SO oils with a control soy oil. A minimum of 24 subjects per group, comprised of at least 12 females and 12 males, were recruited for this study (two control groups, one group each exposed to 30, 45, and 60 g of 23SO, 60g of 4SO, and 60 g 43SO, respectively). Two control groups were included in the study to help account for the anticipated diversity in clinical values in a typical population. The ages ranged from 19 to 63 with a mean age of 35.2 years. Total fat intake from the delivery vehicles for all individuals receiving test or control material was 60 g/day. The total duration of the study was 6 weeks. In weeks 1 and 6 all subjects received control fat (soy oil). In weeks 2–5, the subjects received either control or test fats as assigned per group. The food products were changed weekly on a 2-week cycle to minimize and to assure variety.

Each week of the study, subjects were supplied with food products for consumption during the coming week. Each day, five products were to be integrated into the subjects daily diet; four of the products contained 15 g of control or test oil. One product (crackers or cornflakes) did not deliver test or control oil and was used as a "dummy" carrier. In addition to the food provided by the test vehicles, subjects were free to consume a normal diet, the only restriction being that the amount of alcohol consumption was limited to no more than two 6-oz glasses of wine or two 12-oz servings of beer per day.

After screening, subject selection, and initial check-in, which included drug usage and pregnancy testing (day 0), subjects reported to the clinic on the morning of day 1 to receive products and daily diaries for reporting food consumption and health over the next 7 days. Subjects' weights were also recorded, and blood was drawn for analysis. Subjects returned in the morning every 7 days thereafter (days 8, 15, 22, 28, and 36) to receive food products for the next week, to return daily diaries, to record body weight, and to have blood drawn. On the final day of the study (day 43), subjects returned to the clinic to turn in daily diaries, to be weighed, and to have final samples of blood drawn. All subjects reported to the clinic following a 10-h fast.

Daily diaries were used to record all foods consumed, to rate the palatability of the provided foods, and to record side effects and the quality of daily life. Daily food records included the type and amount of all foods and beverages consumed and the time of day at which each item was consumed. Subject's daily health was assessed in terms of the presence of 15 general categories: fever; changes in exercise tolerance; sneezing, coughing; shortness of breath; gas; nausea; stomach cramps; rashes, itching, hives; tingling in extremities; headaches; dizziness; general weakness; frequent or painful urination; pain or swelling of the joints; and others as specified by the subject. The status of each of these health criteria was rated on a four-point scale: 0, not present; 1, present at an annoyance level but does not interfere with normal functioning; 2, present and is uncomfortable or an embarrassment, impairs normal functioning; 3, present and requires medical assistance, produces a significant impairment of functioning.

All blood samples were assayed for alkaline phosphatase, bilirubin, lactate dehydrogenase (LDH), aspartate aminotransferase (AST), alanine aminotransferase (ALT), γ-glutamyltransferase (GGT), total serum cholesterol, triglyceride, albumin, glucose, blood urea nitrogen (BUN), calcium, chloride, creatinine, iron, phosphorus, sodium, potassium, total protein, and uric acid. All analyses were conducted on a Technicon Axon blood analyzer, Technicon, Tarrytown, NY. Iron was determined on the same instrument using Sigma Ferrozyme reagent, Sigma Chemical Co., St. Louis, MO.

STATISTICAL METHODS

Subject Assignments to Treatment Groups. To assure that all groups were similar at the outset of the study, the subjects were blocked on age, weight, height, frame, sex, enzyme levels (ALT, AST, LDH, GGT, alkaline phosphatase), total bilirubin, and cholesterol levels prior to randomization. The subjects were then randomly assigned to seven treatment groups. The adequacy of the randomization was then confirmed by developing a discriminant function (PROC Discriminant, SAS Institute, 1990a) based on the above parameters. The subjects were then classified into their respective groups using this function. The randomization was considered to be satisfactory when the classification error rate, determined by the discriminant function, exceeded the expected error rate for random numbers (that is, at this error rate all seven groups were considered to be similar at the beginning of the study). Power calculations, based on the variability observed in earlier studies, were made to assure that the size of the treatment groups was sufficient to provide meaningful data.

Assessing Changes in Blood Serum Levels. Multivariate repeated-measures analysis of variance (PROC GLM) (Littell et al., 1991; SAS Institute, 1990a) was employed to measure any changes in the blood components that occurred within each group and between the SALATRIM groups and the controls. Logarithmic transformations were applied to all blood data before the analysis to make the variance more uniform (Winer, 1971). PROC UNIVARIATE (SAS Institute, 1990b) was applied to check the adequacy of the logarithmic transformations. All weekly measurements were tested for significant differences using the baseline measurement (day 8) as a reference. A description of the statistical analyses follows.

Between-Group Analysis. Tests of significance between the SALATRIM groups and each control group, as well as the combined control groups, were made on all 20 blood serum components at weekly intervals. Significant differences occurring between the controls and each of the SALATRIM groups were determined by the GLM procedure in conjunction with the REPEATED and CONTRAST statements (SAS Institute, 1990a). Differences described as not significant imply $P \leq 0.05$.

Within-Group Analysis. Tests of significance between the baseline (day 8) blood serum levels and the weekly measurements occurring within each of the seven groups were determined by the GLM procedure in conjunction with the MANOVA and M=statements (SAS Institute, 1990a). Differences described as not significant imply $P \leq 0.05$.

Assessing Health Status. Chi-square (PROC FREQ) and t tests were used for assessing any changes in the level of clinical symptoms reported on a daily basis for all seven groups, between the pre-exposure, exposure, and post-exposure time periods SAS Institute (1990b).

RESULTS AND DISCUSSION

SALATRIM Composition and Background. The principal acylglycerol components of the SALATRIM family members tested in this study are reported in Table 1. The principal component of SALATRIM 23SO is diacetylstearoylglycerol, whereas in SALATRIM 4SO and 43SO the principal component was dibutyrylstearoylglycerol. Table 1 also summarizes the mono-, di-, and triacylglycerol contents of the three test oils. From the data in Table 1 it can be seen that over 90% of the SALATRIM materials are the expected triacylglycerols, with diacylglycerols being the next most prominent component. The concentrations of inorganics, free fatty acids, and tocopherols were within ranges of other food oils (data not shown).

Clinical Chemistry Results. Most clinical parameters measured failed to show any clinically important changes over time. Only the clinical chemistry results that did show statistically significant differences between the SALATRIM and control groups during the study are

Table 3. Significance between the Controls and the Treatment Groups[a]

	levels of significance (P values)					
		23SO			4SO	43SO
factor	overall significance[d]	30 g	45 g	60 g	60 g	60 g
alanine aminotransferase						
separate controls	0.0001					
control 1[b]		NS[c]	NS	0.0052	0.0001	0.0049
control 2		NS	NS	0.0062	0.0001	0.0047
combined	0.0001	NS	NS	0.0010	0.0001	0.0014
aspartate aminotransferase						
separate controls	0.0038					
control 1		NS	NS	NS	0.0031	0.0154
control 2		NS	NS	0.0483	0.0020	0.0051
combined	0.0015	NS	NS	0.0189	0.0004	0.0032
alkaline phosphatase						
separate controls	0.0001					
control 1		0.0095	0.0123	0.0011	0.0012	0.0008
control 2		0.0034	0.016	0.0023	0.0072	0.0004
combined	0.0001	0.0009	0.0007	0.0002	0.0004	0.0001
γ-glutamyltransferase						
separate controls	0.0680					
control 1		NS	NS	NS	NS	NS
control 2		NS	NS	NS	NS	NS
combined	0.0322	NS	NS	NS	0.0378	NS
creatinine						
separate controls	0.0460					
control 1		0.0178	NS	NS	NS	NS
control 2		NS	NS	NS	NS	NS
combined	0.0230	0.0145	NS	NS	NS	0.0487
uric acid						
separate controls	0.0779					
control 1		NS	NS	NS	NS	NS
control 2		NS	NS	NS	NS	NS
combined	0.0385	NS	NS	NS	0.0099	0.0279
cholesterol						
separate controls	0.0266					
control 1		NS	NS	NS	NS	0.0008
control 2		NS	NS	NS	NS	0.0020
combined	0.0196	NS	NS	NS	NS	0.0003
calcium						
separate controls	0.0056					
control 1		NS	NS	NS	NS	NS
control 2		0.0190	0.0166	0.0084	NS	0.0011
combined	0.0105	NS	NS	NS	NS	0.0128

[a] Table based on subjects completing the study. [b] Subjects/treatment group: control 1, 25; control 2, 24; combined controls, 49; 23SO 30 g, 23; 23SO 45 g, 22; 23SO 60 g, 23; 4SO 60 g, 19; 43SO 60 g, 13. [c] NS, not significant at $P \leq 0.05$. [d] Time × treatment effect.

reported in this section. Of the 183 subjects starting the study, 149 completed it. The data presented include only the results for the subjects completing the study. The current study was designed to confirm the previously reported increase in serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) activities observed when the subjects were exposed to SALATRIM (Finley et al., 1994b) over extended periods of time. While we were primarily interested in the AST and ALT results, 8 of the 20 serum chemistry determinations showed statistically significant differences between the controls and SALATRIM groups. These differences, as well as the within-group differences observed in the eight serum chemistry determinations, are discussed below.

In Table 2 the trends in the mean values for AST and ALT and other clinical chemistry parameters are compared to the normal limits of each test as conducted at Harris Laboratories. The significant differences within each group over time, as determined by multivariate repeated-measures analysis of variance, are designated by the superscripts in the table. All weekly measurements within each group are compared to day 8, which was the end of the pre-exposure period (or baseline). Transient increases in the AST and ALT levels over time were observed in both the controls and all SALATRIM groups. However, in the 60-g SALATRIM groups, the magnitudes of the increases in ALT and AST levels from the day 8 baseline were greater than that observed in the control groups. By the end of the 4-week exposure periods, the AST and ALT activities in all groups approached values equivalent to those of day 8. It is important to note that none of the group means ever exceeded the normal clinical limits for AST or ALT.

In Table 3 the level of significance between the controls and the SALATRIM groups having overall P values <0.05 is presented. The ALT and AST values in the 60-g SALATRIM groups were significantly different from the controls because greater increases in the values occurred initially after day 8. The ALT and AST values in the 60-g SALATRIM groups decreased as the study progressed, and at the end of the study nearly all of the values were similar to the baseline values. It is important to note that the ALT and AST levels of the 30- and 45-g SALATRIM groups were never significantly different from the controls. The alkaline phosphatase differences were statistically significant because of a slight consistent increase in values in the control groups and decrease in the values in the SALATRIM groups. The significant differences observed in the other components listed in Table 3 are small and not considered to be of clinical importance. Nearly all of the subjects remained well within the expected ranges for normal individuals throughout the study.

No significant differences were observed between the two controls for any of the 20 clinical chemistry parameters;

Table 4. Health Status of Subjects Dropping out of Study

study group	drop week	subject	sex	days with cramps	days with gas	days with headache	days with nausea	reason for dropping out	AST[a] initial	AST[a] final	ALT[b] initial	ALT[b] final
control 1	5	189	M	0	0	6	0	illness	16	18	15	18
control 2	2	640	F	0	0	0	0	adverse effects	19	17	14	14
	3	420	F	0	0	0	0	adverse effects	21	18	29	19
23SO 30 g	1	625	F	0	0	0	0	excess alcohol	21	21	39	39
	3	336	M	0	14	0	0	illness	18	21	27	32
	4	82	F	5	3	4	4	adverse effects	15	15	14	14
	5	450	F	0	1	0	0	no show	21	17	15	13
23SO 45 g	2	229	F	0	1	7	0	adverse effects	23	22	13	13
	2	666	M	0	0	0	0	failed requirements	29	23	42	36
	3	493	F	0	0	0	0	illness	19	19	12	18
	3	15	F	0	0	0	0	adverse effects	17	19	15	17
	4	545	M	2	7	1	6	adverse effects	19	24	24	35
23SO 60 g	2	115	M	0	0	0	0	adverse effects	17	20	20	32
	1	94	F	0	0	2	0	use of medications	17	17	23	23
	2	62	M	0	0	0	0	adverse effects	30	24	27	19
4SO 60 g	2	514	M	0	0	0	0	adverse effects	18	18	28	20
	3	89	F	0	0	0	0	adverse effects	11	19	9	21
	2	430	M	1	1	0	0	adverse effects	19	19	15	15
	2	77	M	0	0	0	0	adverse effects	26	26	28	27
	4	390	M	0	1	0	1	adverse effects	17	20	19	29
	2	632	F	0	0	0	0	no show at day 15	16	15	15	13
	1	747	M	0	0	0	0	no show at day 8	15	15	24	24
43SO 60 g	2	9	M	0	0	0	0	illness	21	15	19	14
	2	577	F	0	0	0	0	adverse effects	16	20	17	21
	2	356	F	1	2	0	1	adverse effects	17	17	13	13
43SO 60 g	2	46	F	0	0	0	0	adverse effects	17	18	22	23
	2	326	M	0	0	1	0	adverse effects	28	24	32	27
	3	489	M	4	3	4	1	adverse effects	13	13	18	24
	2	529	M	0	0	0	0	adverse effects	23	23	30	38
	5	68	F	13	10	1	15	adverse effects	12	15	15	24
	4	322	M	3	1	0	11	adverse effects	21	20	20	25
	5	564	F	11	5	2	12	adverse effects	19	27	16	31
	6	97	F	4	5	3	4	moved	14	18	15	25

[a] Normal value range for AST is 4–36. [b] Normal value range for ALT is 0–49.

Table 5. Reported Incidence and Intensity of Stomach Cramps (Percent Subject Days)

treatment group	pre-exposure period[a] absent[c]	pre-exposure period[a] annoy[d]	pre-exposure period[a] uncomf[e]	pre-exposure period[a] impair[f]	exposure period[b] absent	exposure period[b] annoy	exposure period[b] uncomf	exposure period[b] impair	post-exposure period[a] absent	post-exposure period[a] annoy	post-exposure period[a] uncomf	post-exposure period[a] impair
control 1, $n = 25$	100.00	0.00	0.00	0.00	97.85	1.86	0.29	0.00	96.00	3.43	0.57	0.00
control 2, $n = 24$	96.43	2.98	0.60	0.00	97.17	1.79	1.04	0.00	94.64	4.17	1.19	0.00
23SO 30 g,[g] $n = 23$	98.05	1.30	0.65	0.00	91.23	6.17	2.60	0.00	99.35	0.65	0.00	0.00
23SO 45 g,[g] $n = 22$	97.28	1.36	1.36	0.00	90.65	5.44	2.72	1.19	87.76	5.44	6.80	0.00
23SO 60 g,[g] $n = 23$	96.88	1.88	1.25	0.00	83.20	14.15	2.64	0.00	98.14	1.86	0.00	0.00
4SO 60 g,[g] $n = 19$	96.24	3.76	0.00	0.00	80.34	13.80	5.10	0.76	90.98	9.02	0.00	0.00
43SO 60 g,[g] $n = 13$	100.00	0.00	0.00	0.00	79.40	11.26	8.52	0.82	98.90	1.10	0.00	0.00

[a] Number of subject days for the pre-exposure and post-exposure periods = 7 days × number of subjects in group. [b] Number of subject days for exposure period = 28 days × number of subjects in group. [c] Absent, stomach cramps not present. [d] Annoy, stomach cramps present at an annoyance level but do not interefere with normal functioning. [e] Uncomf, stomach cramps present and uncomfortable or an embarrassment, impair normal functioning. [f] Impair, stomach cramps present and require medical assistance; produces a significant impairment of functioning. [g] Significant differences exist among the three periods at $P \leq 0.05$.

therefore, comparisons between the combined control groups and the SALATRIM groups were also made. When the two control groups were combined, similar conclusions were drawn, thus suggesting that all statistically significant differences between the control and SALATRIM groups had been identified.

Several individuals failed to complete the study for a variety of reasons. The number of subjects completing the study in each group follow: control 1, 25 of 26; control 2, 24 of 27; 23SO 30 g, 23 of 27; 23SO 45 g, 22 of 27; 23SO 60 g, 23 of 25; 4SO 60 g, 19 of 25; 43SO 60 g, 13 of 25. Table 4 reports the week the subjects withdrew, the clinical symptoms to that point, the reason for withdrawing from the study, and the initial and final AST and ALT levels. Adverse effects were cited as the most common reason for dropping out of the study. The AST and ALT results suggest that the transaminase activity in the subjects who withdrew was similar to that of subjects who remained in the study. No differences of clinical interest were observed in the other chemistry analyses.

Body Weights. No subjects had a weight loss greater than 2 kg over the course of study. In control group 1 only, a slight but statistically significant increase in mean body weight after 5 weeks was observed and it remained significant at the end of the study.

Clinical Symptoms. In our earlier study (Finley et al., 1994a) subjects consuming 60 g/day SALATRIM reported increased incidence of headache and gastrointestinal upset compared to periods when they were consuming control fats. In the present study, daily diary questionnaires completed by the subjects were assessed to determine if the consumption of SALATRIM impacted health and well-being. Clinical symptoms were statistically assessed for differences in occurrence between the pre-exposure, test period, and post-exposure periods of the study. The incidence of headaches was not significantly

Table 6. Reported Incidence and Intensity of Nausea (Percent Subject days)

	pre-exposure period[a]				exposure period[b]				post-exposure period[a]			
treatment group	absent[c]	annoy[d]	uncomf[e]	impair[f]	absent	annoy	uncomf	impair	absent	annoy	uncomf	impair
control 1, $n = 25$	98.86	1.14	0.00	0.00	97.42	1.72	0.72	0.14	96.57	1.71	0.57	1.14
control 2, $n = 24$	99.40	0.60	0.00	0.00	99.85	0.15	0.00	0.00	97.62	2.38	0.00	0.00
23SO 30 g,[g] $n = 23$	100.00	0.00	0.00	0.00	89.60	8.07	2.33	0.00	95.03	3.73	1.24	0.00
23SO 45g,[g] $n = 22$	97.96	1.36	0.68	0.00	89.44	8.01	1.87	0.68	87.07	8.16	4.76	0.00
23SO 60 g,[g] $n = 23$	98.75	1.20	0.00	0.00	81.18	13.84	4.67	0.31	91.93	8.07	0.00	0.00
4SO 60 g,[g] $n = 19$	96.24	2.26	0.75	0.75	79.25	15.47	4.53	0.75	90.23	9.77	0.00	0.00
43SO 60 g,[g] $n = 13$	100.00	0.00	0.00	0.00	75.48	14.88	9.09	0.55	96.70	3.30	0.00	0.00

[a] Number of subject days for the pre-exposure and post-exposure periods = 7 days × number of subjects in group. [b] Number of subject days for exposure period = 28 days × number of subjects in group. [c] Absent, nausea not present. [d] Annoy, nausea present at an annoyance level but does not interefere with normal functioning. [e] Uncomf, nausea present and uncomfortable or an embarrassment, impairs normal functioning. [f] Impair, nausea present and requires medical assistance; produces a significant impairment of functioning. [g] Significant differences exist among the three periods at $P \leq 0.05$.

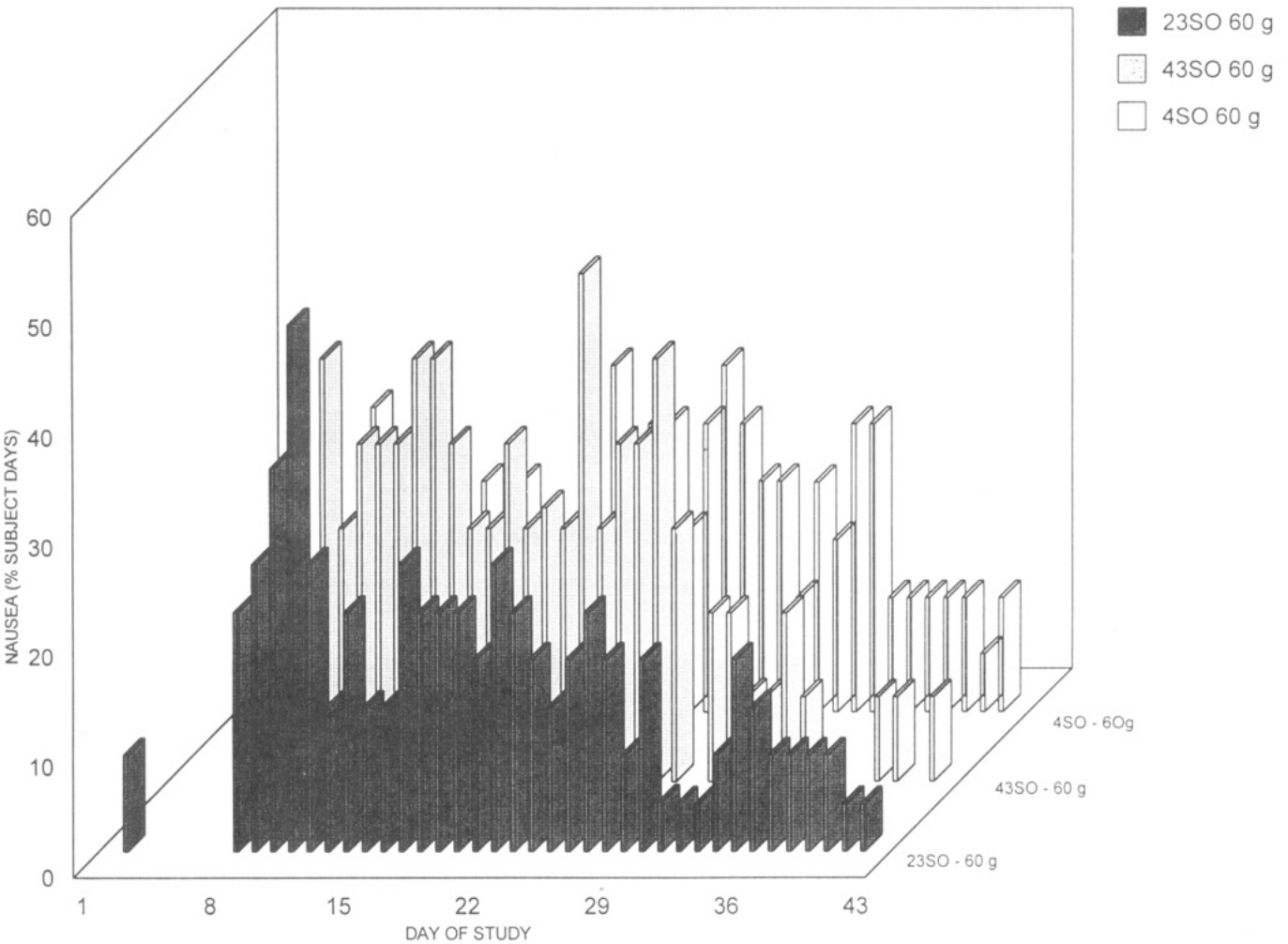

Figure 1. Reported incidence of nausea (percent subject days).

increased during the period when subjects were exposed to SALATRIM, as had been suggested in earlier studies (Finley et al., 1994b). The only important clinical effects which seemed to be associated with SALATRIM consumption were nausea and stomach cramps.

In Tables 5 and 6 the incidence and intensity of the nausea and cramp symptoms reported during the pre-, post-, and exposure periods are presented. From these tables it can be seen that consumption of 60 g/day SALATRIM was generally associated with more reports of cramps and nausea in a substantial number of subjects. At 45 g/day 23SO, the reported incidence was lower. When subjects consumed 30 g/day SALATRIM 23SO, there were no reported incidences of nausea which impaired daily function. It is important to note that 30 g/day is the expected 90th percentile consumption for users if SALATRIM were included at 100% substitution in dairy products, cookies, crackers, chocolates, and confections, snacks, margarine, and spreads. The results, therefore, suggest that at normal levels of consumption (i.e., <30 g/day) SALATRIM would be expected to be without effect. It is also interesting to observe that the reports of nausea were much greater when different delivery vehicles were introduced into the diet.

Figure 1 illustrates the incidence of nausea symptoms reported by subjects exposed to 60 g/day SALATRIM over the course of the study. From the graph it can be seen that after days 8, 15, 22, and 29 there appears to be increased incidence of nausea reported for 3 or 4 days followed by a general decline. Also, it can be seen that by

the end of the exposure period (day 36), the incidence of nausea had decreased. There was a general trend across all groups for the incidence of nausea to be highest on the second day after the introduction of new delivery vehicles. This graph suggests that the change in food vehicles may be partially responsible for the observed nausea symptoms.

An increase in nausea and stomach cramps can be expected when subjects abruptly change from normal diet to diets containing substantial amounts of undigestible or poorly digestible material. Pilch (1987) summarized several reports that demonstrate that abrupt increase in dietary fiber carried transient gastrointestinal symptoms. Therefore, it would be predictable that when high levels of SALATRIM or other low-calorie products are introduced into the diet, subjects would experience some transient effects.

Conclusions. The results of this study indicate that AST and ALT activities showed the anticipated transient changes as a consequence of exposure to SALATRIM at high levels; however, the increases are within the normal expected range and are not of clinical concern. Only minor changes in blood chemistry were observed as a consequence of SALATRIM exposure. Nausea and stomach cramps were significantly higher during the exposure period for subjects consuming high levels of SALATRIM and were frequently associated with changes in delivery vehicles. This observation suggests that the symptoms observed might be expected from the overconsumption of any food, particularly a food with limited digestibility. Our overall conclusion based on the data presented here is that SALATRIM, when consumed at the anticipated levels of consumption or at the anticipated 90th percentile level of intake, will have little or no effect on the health of individuals consuming SALATRIM.

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LITERATURE CITED

Finley, J. W.; Klemann, L. P.; Leveille, G. A.; Otterburn, M. S.; Walchak, C. G. Caloric Availability of SALATRIM in Rats and Humans. *J. Agric. Food Chem.* **1994a**, one of several papers in this issue.

Finley, J. W.; Leveille, G. A.; Dixon, R. M.; Walchak, C. G.; Sourby, J. C.; Smith, R.E.; Francis, K.; Otterburn, M. S. Clinical Assessment of SALATRIM: A Reduced Calorie Triacylglycerol *J. Agric. Food Chem.* **1994b**, one of several papers in this issue.

Huang, A.; Delano, G. M.; Pidel, A.; Janes, L. E.; Softly, B. J.; Templeman, G. J. Identification and Quantification of SALATRIM 23CA in Foods by the Combination of Supercritical Fluid Extraction, Particle Beam LC–Mass Spectrometry, and HPLC with Light-Scattering Detector. *J. Agric. Food Chem.* **1994a**, one of several papers in this issue.

Huang, A.; Robinson, L. R.; Gursky, L.; Perfita, R.; Sabidong, C. Identification and Quantification of SALATRIM 23CA in Foods by the Combination of Supercritical Fluid Extraction, Particle Beam LC-Mass Spectrometry, and HPLC with Light Scattering Detector. *J. Agric. Food Chem.* **1994b**, one of several papers in this issue.

IUPAC. Commission on Oils, Fats and Derivative, Determination of Triglycerides in Fats and Oils: results of A Collaborative Study and the Standard Method. *Pure Appl. Chem.* **1985**, *57*, 1516–1522.

Klemann, L. P.; Aji, K.; Chrysam, M.; D'Amelia, R. P.; Henderson, J.; Huang, A.; Otterburn, M. S.; Yarger, R. G.; Boldt, G.; Roden, A. Random Nature of Triacylglycerols by the Catalyzed Interesterification of Short- and Long-Chain Fatty Acid Triglycerides. *J. Agric. Food Chem.* **1994**, one of several papers in this issue.

Littell, R. C.; Freund, R. J.; Spector, P. C. *SAS System for Linear Models*, 3rd ed.; SAS Institute: Cary, NC, 1991; pp 252–257.

Pilch, S. M. "Physiological Effects and Health Consequences of Dietary Fiber"; Report FDA/CFSAN-87/48; Life Sciences Research Office, Bethesda, MD, June 1987.

Richardson, G. H. 18.8 Fat. In *Standard Methods for the Examination of Dairy Products*; American Public Health Association: Washington, DC, 1985; p 355.

SAS Institute. *SAS/STAT User's Guide*, version 6, 4th ed.; SAS Institute: Cary, NC, 1990a; Vol. 1.

SAS Institute. *SAS/STAT User's Guide*, version 6, 4th ed.; SAS Institute: Cary, NC, 1990b, Vol. 2.

Winer, B. J. Design and Analysis of Factorial Experiments. In *Statistical Principles in Experimental Design*; McGraw-Hill: New York, 1971; p 401.

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