

KINETICS AND SAFETY OF  
SOY LECITHIN PHOSPHATIDYLSERINE (PS)  
ABSORPTION.

Study Report, September 1, 1999.

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This document is an overview of confidential proprietary clinical trials data conducted with the Lipogen Ltd. soy lecithin phosphatidylserine (PS) complex. The statements in this document have not been evaluated by the Food And Drug Administration. No claims are made herein for any particular product or that any product is intended to diagnose, treat, cure, or prevent any disease.

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### General.

This report summarizes results of a study on the kinetics of soy lecithin phosphatidylserine (PS) absorption by the body. The study was carried out in July 1996 with standard soft gelatin capsules containing soy lecithin PS complex supplied by Lipogen Ltd. in Israel.

In this study we can conclude the following:

- f* The capsules disintegrated after 30 minutes.
- f* The PS was well tolerated by the body. The basal serum level was reached after 180 minutes from intake.
- f* No side effects were reported in this trial.

The studied soy lecithin phosphatidylserine complex is considered as food supplement (lecithin and other phospholipids). The product is freely sold as an OTC product (Israel, Europe, USA, etc.).

This is a confidential. The information included in this report is not to be disclosed in any form nor be subjected to any public exposure whatsoever.

### Study procedure.

Eight (8) healthy volunteers, age 28-52, participated in the study. Each participant received 5 standard soft gelatin capsules containing soy lecithin PS complex (100mg. PS per capsule). 5ml. of venous blood were drawn from each participant at each point of measurement (every 30 minutes from intake). The plasma was separated immediately after blood drawing and 1ml. of plasma was then mixed with 9ml. of isopropanol and then with 10ml. of chloroform, for exhaustive extraction of serum lipids. The mixture was then centrifuged and the clear and homogeneous lipid extract was collected. It included approximately 100µg/ml phospholipids. Analysis of the individual phospholipids was carried out by 2 dimensional thin layer chromatography on silica gel plates with chloroform - methanol - ammonia (65:35:5) as first running solvent. Second running solvent was chloroform - acetic acid - acetone - water (60:30:10:10:5). Each phospholipid spot was scraped off and processed for phosphorus analysis. The ratio of the phosphorus in the PS spot over the sum of phosphorus of all phospholipid spots (PS/PL) was taken as the measure of PS level in the plasma.

All participants were examined in the morning after overnight fast. The PS/PL level before the intake (time 0) was in the range of 1.8% - 2.2%. Immediately after time 0 each participant swallowed 5 standard soft gelatin capsules containing soy lecithin PS complex (total of 500mg. PS). In each of them, blood was drawn 30, 60, 90, 150 and 180 minutes after intake. In all participants, a peak value of PS/PL appeared at 90 minutes after

intake. Table1 below presents the readings of the measured PS serum level (in % of total phospholipids) in 8 volunteers after intake of 5 capsules of soy lecithin phosphatidylserine complex.

subject	gender	age	PS serum level (% of total PL) after intake (time in minutes)						
			000	030	060	090	120	150	180
D.C.	F	39	2.20	2.10	2.65	4.15	4.00	2.50	2.40
R.H.	F	41	2.25	2.45	3.30	4.05	4.05	2.95	2.30
Z.A.	M	28	2.20	2.30	2.50	3.90	3.30	3.25	2.60
I.P.	M	42	2.15	1.90	3.00	3.60	3.30	2.90	2.10
D.R.	M	43	2.20	2.05	3.60	4.20	3.00	2.50	2.05
D.A.	M	48	2.15	2.10	3.05	4.05	4.00	3.20	2.00
A.S.	M	51	2.05	1.90	2.80	3.70	3.60	3.00	1.95
M.S.	M	52	1.60	2.00	2.30	3.95	2.36	2.30	2.20
Mean			2.15	2.10	2.90	3.95	3.45	2.82	2.20

Table. 1.

The overall average profile of the PS/PL values attained in this test is shown in the figure 1 below. No adverse effects or any discomfort were reported by the participants.

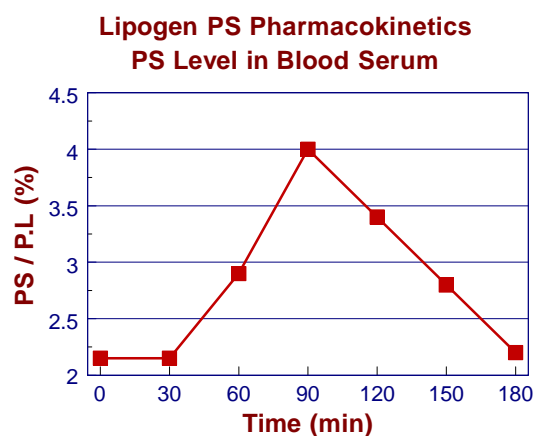


Fig. 1.

## Conclusions

The following conclusions can be drawn:

- f* The PS capsules disintegrate after 30 minutes.
- f* The PS was well tolerated by the body. The basal level returned after some 180 minutes from intake.
- f* No side effects were reported in this trial.