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List of references supporting the assessment of *Glycine max* (L.) Merr., lecithinum

Final

The European Medicines Agency acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.

Bell JM, Lundberg PK. Effects of a commercial soy lecithin preparation on development of sensorimotor behavior and brain biochemistry in the rat. *Dev Psychobiol* 1985, 18(1): 59-66

Bell JM, Slotkin TA. Perinatal dietary supplementation with a commercial soy lecithin preparation: effects on behavior and brain biochemistry in the developing rat. *Dev Psychobiol* 1985, 18(5): 383-394

Blumenthal M, Goldberg A, Brinckmann J, editors. *Herbal Medicine. Expanded Commission E Monographs*. The American Botanical Council, Austin Texas 2000, 354-358

Bruneton J. *Pharmacognosy, Phytochemistry, Medicinal Plants*, 2nd ed, Lavoisier Publishing, France 1999, 147-149

Das SK, Vasudevan DM. Effect of lecithin in the treatment of ethanol mediated free radical induced hepatotoxicity. *Indian J Clin Biochem* 2006, 21(1):62-69

Der Marderosian A, Beutler J. [The Review of Natural Products. Monograph: Lecithin. Facts and Comparisons, A Wolters Kluwer Company, http://online.statref.com/](http://online.statref.com/), created July 17, 2007; modified December 18, 2014. Accessed 26/5/2015

European Medicines Agency (EMA). Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein. (EMEA/HMPC/138139/2005)

European Medicines Agency (EMA). Guideline on clinical investigation of medicinal products in the treatment of lipid disorders (EMA/CHMP/748108/2013)

Gundermann KJ, Kuenker A, Kuntz E, Droździk M. Activity of essential phospholipids (EPL) from soybean in liver diseases. *Pharmacol Rep* 2011, 63(3): 643-659

Honda K, Enoshima T, Oshikata T, Kamiya K, Hamamura M, Yamaguchi N et al. Toxicity studies of Asahi Kasei PI, purified phosphatidylinositol from soy lecithin. *J Toxicol Sci* 2009, 34(3): 265-280



Hunt CE, Duncan LA. Hyperlipoproteinaemia and atherosclerosis in rabbits fed low-level cholesterol and lecithin. *Br J Exp Pathol* 1985, 66: 35–46

Hänsel R., Keller K., Rimpler H., Schneider G, editors, Hagers Handbuch der Pharmazeutischen Praxis, Drogen E-O. Vol 5. 5th ed. Springer-Verlag, Berlin 1993, 300-311

Jenkins PJ, Portmann BP, Eddleston AL, Williams R. Use of polyunsaturated phosphatidyl choline in HBsAg negative chronic active hepatitis: results of prospective double-blind controlled trial. *Liver* 1982, 2(2): 77-81

Jimenez MA, Scarino ML, Vignolini F, Mengheri E. Evidence that polyunsaturated lecithin induces a reduction in plasma cholesterol level and favorable changes in lipoprotein composition in hypercholesterolemic rats. *J Nutr* 1990, 120: 659–667

Kesaniemi YA, Grundy SM. Effects of dietary polyenylphosphatidylcholine on metabolism of cholesterol and triglycerides in hypertriglyceridemic patients. *Am J Clin Nutr* 1986, 43(1): 98-107

Kirsten R, Heintz B, Nelson K, Oremek G. Reduction of hyperlipidemia with 3-sn-polyenylphosphatidylcholine in dialysis patients. *Int J Clin Pharmacol Ther Toxicol* 1989, 27(3): 129-134

Kirsten R, Heintz B, Nelson K, Hesse K, Schneider E, Oremek G, Nemeth N. Polyenylphosphatidylcholine improves the lipoprotein profile in diabetic patients. *Int J Clin Pharmacol Ther* 1994, 32(2): 53-56

Lieber CS, Weiss DG, Groszmann R, Paronetto F, Schenker S, II Veterans affairs cooperative study of polyphosphatidylcholine in alcoholic liver disease. *Alcohol Clin Exp Res* 2003, 27(11): 1765-1772

Lim W. Antiphospholipid syndrome. *Hematology Am Soc Hematol Educ Program* 2013, 2013: 675-680

Martindale. The Extra Pharmacopoeia. 29th ed. The Pharmaceutical Press, London 1989, 1274-1275

Niederau C, Strohmeyer G, Heintges T, Peter K, Göpfert E. Polyunsaturated phosphatidyl-choline and interferon alpha for treatment of chronic hepatitis B and C: a multicenter, randomized, double-blind, placebo-controlled trial. *Hepatogastroenterology* 1998, 45(21): 797-804

O'Brien BC, Corrigan SM. Influence of dietary soybean and egg lecithins on lipid responses in cholesterol-fed guinea pigs. *Lipids* 1988, 23(7): 647-650

O'Mullane JE, Hawthorne JN. A comparison of the effects of feeding linoleic acid-rich lecithin or corn oil on cholesterol absorption and metabolism in the rat. *Atherosclerosis* 1982, 45(1): 81-90

Raj PV, Nitesh K, Prateek J, Sankhe MN, Rao JV, Rao CM, Udupa N. Effect of lecithin on d-galactosamine induced hepatotoxicity through mitochondrial pathway involving Bcl-2 and Bax. *Ind J Clin Biochem* 2011, 26(4): 378-384

Singh NK, Prasad RC. A pilot study of polyunsaturated phosphatidyl choline in fulminant and subacute hepatic failure. *JAPI* 1998, 46(6): 530-532

Steinegger E, Hänsel R. Lehrbuch der Pharmakognosie. Springer Verlag Berlin-Heidelberg-New York 1972, 361-364

Suzuki S, Yamatoya H, Sakai M, Kataoka A, Furushiro M, Kudo S. Oral administration of soybean lecithin transphosphatidylated phosphatidylserine improves memory impairment in aged rats. *J Nutr* 2001, 131(11): 2951-2956

ter Welle HF, van Gent CM, Dekker W, Willebrands AF. The effect of soya lecithin on serum lipid values in type II hyperlipoproteinemia. *Acta Med Scand* 1974, 195(4): 267-271

Turecky L, Kupcova V, Szantova M, Uhlikova E. Plasma lipid parameters in patients with alcoholic fatty liver after treatment with essential phospholipids. *Bratisl Lek Listy* 2003, 104(7-8): 227-231

Tuthill JI, Khamashta MA. Management of antiphospholipid syndrome. *J Autoimmun* 2009, 33(2): 92-98

van Ee J.H. Soy constituents: Modes of action in low-density lipoprotein management. *Nutrition Reviews* 2009, 67(4): 222-234

Wilson TA, Meservey CM, Nicolosi RJ. Soy lecithin reduces plasma lipoprotein cholesterol and early atherogenesis in hypercholesterolemic monkeys and hamsters: beyond linoleate. *Atherosclerosis* 1998, 140(1): 147-153

Wong EK, Nicolosi RJ, Low PA, Herd JA, Hayes K. Lecithin influence on hyperlipemia in rhesus monkeys. *Lipids* 1980, 15: 428-433

Zierenberg O, Grundy SM. Intestinal absorption of polyenephosphatidylcholine in man. *J Lipid Res* 1982, 23: 1136-1142

Excluded non-clinical studies

Chandrasiri V, Villaume C, Bau HM, Mejean L. Effects of the nature of dietary proteins, lecithin and methionine on rat plasma lipids. *Arch Int Physiol Biochim Biophys* 1991, 99(4): 291-295

Ishida T, Koba K, Sugano M, Imaizumi K, Watanabe S, Minoshima R. Cholesterol levels and eicosanoid production in rats fed phosphatidylinositol or soybean lecithin. *J Nutr Sci Vitaminol (Tokyo)* 1988, 34(2): 237-244

Excluded clinical studies

Brook JG, Linn S, Aviram M. Dietary soya lecithin decreases plasma triglyceride levels and inhibits collagen- and ADP-induced platelet aggregation. *Biochem Med Metab Biol* 1986, 35(1): 31-39

Childs MT, Bowlin JA, Ogilvie JT, Hazzard WR, Albers JJ. The contrasting effects of a dietary soya lecithin product and corn oil on lipoprotein lipids in normolipidemic and familial hypercholesterolemic subjects. *Atherosclerosis* 1981, 38(1-2): 217-228

Cobb M, Turkki P, Linscheer W, Raheja K. Lecithin supplementation in healthy volunteers: effect on cholesterol esterification and plasma, and bile lipids. *Nutr Metab* 1980, 24(4): 228-237

Galli C, Tremoli E, Giani E, Maderna P, Gianfranceschi G, Sirtori CR. Oral polyunsaturated phosphatidylcholine reduces platelet lipid and cholesterol contents in healthy volunteers. *Lipids* 1985, 20(9): 561-566

Greten H, Raetzer H, Stiehl A, Schettler G. The effect of polyunsaturated phosphatidylcholine on plasma lipids and fecal sterol excretion. *Atherosclerosis* 1980, 36(1): 81-88

Høie LH, Morgenstern EC, Gruenwald J, Graubaum HJ, Busch R, Lüder W, Zunft HJ. A double-blind placebo-controlled clinical trial compares the cholesterol-lowering effects of two different soy protein preparations in hypercholesterolemic subjects. *Eur J Nutr* 2005, 44(2): 65-71

Knuiman JT, Beynen AC, Katan MB. Lecithin intake and serum cholesterol. *Am J Clin Nutr* 1989, 49(2): 266-268

Mensink RP, Zock PL, Kester AD, Katan MB. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *Am J Clin Nutr* 2003, 77(5): 1146-1155

Mourad AM, de Carvalho Pincinato E, Mazzola PG, Sabha M, Moriel P. Influence of soy lecithin administration on hypercholesterolemia. *Cholesterol* 2010

Oosthuizen W, Vorster HH, Vermaak WJ, Smuts CM, Jerling JC, Veldman FJ, Burger HM. Lecithin has no effect on serum lipoprotein, plasma fibrinogen and macro molecular protein complex levels in hyperlipidaemic men in a double-blind controlled study. *Eur J Clin Nutr* 1998, 52(6): 419-424

Simons LA, Hickie JB, Ruys J. Treatment of hypercholesterolaemia with oral lecithin. *Aust N Z J Med* 1977, 7(3): 262-266

Sirtori CR, Zucchi-Dentone C, Sirtori M, Gatti E, Descovich GC, Gaddi A, Cattin L, Da Col PG, Senin U, Mannarino E. Cholesterol-lowering and HDL-raising properties of lecithinated soy proteins in type II hyperlipidemic patients. *Ann Nutr Metab* 1985, 29(6): 348-357

Tompkins RK, Parkin LG. Effects of long-term ingestion of soya phospholipids on serum lipids in humans. *Am J Surg* 1980, 140(3): 360-364

Wojcicki J., Pawlik A., Samochowiec L., Kaldonska M., Mysiliwiec Z. Clinical evaluation of lecithin as a lipid-lowering agent. *Phytotherapy Research* 1995, 9(8): 597-599