MONOGRAPH ON LECITHIN #121 Vol I

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LECITHIN

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DEPARTMENT OF HEALTH, EDUCATION
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SUMMARY

Acute Toxicity

No information on the acute toxicity of lecithin has been found. As can be seen in the section on short-term studies, the ingestion of soybean lecithin is well-tolerated by man.

Short-term Studies

Geyer *et al*. (0968) observed a vasodepressor activity when commercial soybean phosphatides were administered i.v. to cats. They concluded this was the result of degradative or oxidative changes following manufacture since little such activity was found with freshly prepared material. The authors pointed out that man was also sensitive to this vasodepressor effect. The fact that commercial lecithin contains a potent vasodepressor substance is noted in the Merck Index (2677)

Davis (0633) found that prolonged daily administration p.o. of 5 g lecithin to dogs decreased their erythrocyte numbers 15 to 20 percent. They returned to normal within a few weeks after cessation of lecithin feeding.

Steiner and Domanski (2693) found that feeding 25 g "soya lecithin" daily for six weeks to eight patients caused no unusual symptoms. For five of the eight weeks their serum cholesterol was significantly lowered.

Tompkins *et al*. (2807) found that ingestion of 48 g daily of commercial soybean lecithin for one year was well-tolerated. No renal cardiovascular or hepatic changes were observed. Serum cholesterol and triglycerides were lowered.

Long-term Studies

None were found in the literature.

Special Studies

Altman *et al*. (0071) found that the administration s.c. of soybean phosphatide along with the carcinogen

methylcholanthrene retarded tumor appearance in mice.

Downs (0720) found that rabbits fed small doses of lecithin (3 or 6 grains) along with cholesterol and/or vitamin D did not develop vascular changes.

Davis (0632) found that p.o. administration of 3 g soybean lecithin to polycythemic dogs significantly reduced their erythrocyte counts with no appreciable change in leukocyte counts despite continuation of hemopoietic stimulating measures.

Tompkins (2805) reported that oral lecithin administration to patients with cholelithiasis on a diet low in fat and cholesterol raised their biliary phospholipid to cholesterol ratio closer to that found in normal persons.

Absorption and Distribution

In rodents dietary lecithin is reportedly hydrolysed and absorbed as lysolecithin, then partly reconverted to lecithin and incorporated into chylomicrons (2507).

Metabolism and Excretion

Lecithin reportedly may contribute to synthesis of cholesteryl esters by an acyltransferase reaction but the importance of this was uncertain (0989). Its excretion, mainly in bile (2469), appeared to be coupled to that of cholesterol (2967), but no definitive reports were found on the fate of ingested soybean lecithins separately from endogenous lecithins.

Metabolic Effects

In rats, lecithin reportedly has promoted absorption of fats but not through its emulsifying action (2787). Contradictory data are reported on atherogenicity (0968). In dogs, soy lecithin i.v. apparently stimulated insulin release and glucose absorption (0587).

Drug Interactions

Consistent, confirmed reports were not found.

Consumer Exposure

Lecithins are extensively employed in food processing as antioxidants, and emulsifying, dispersing, wetting, penetrating, and solubilizing agents (0563).

Estimated daily intakes of lecithin from the average diet range from 395 to 2034 mg, depending on the age level; maximum daily intakes are estimated to be 780 to 5267 mg (0869). Lecithin is used in food processing at levels ranging from 0.0025% in prepared breakfast cereals to amounts sufficient for the purpose in lard and shortenings (0866). The maximum use level in foods included in the GRAS Survey was approximately 2% (wtd. mean) in imitation dairy products (0867). The Joint FAO/WHO Expert Committee on Food Additives estimated acceptable daily intakes AID's for man to be 0-50 mg/kg BW (unconditional) and 50-100 mg/kg BW (conditional) in addition to the daily intake in the usual diet of 1-5 grams (1305). The annual poundage reported to NAS and FEMA for 1970 was 9,128,905 (0871)

The estimated daily intake of lecithin modified with hydrogen peroxide from the average daily diet ranges from 16 to 513 mg, in accordance with age; estimated maximum daily intakes range from 21 to 809 mg. The maximum use level reported was 0.44% (wtd mean) in baked goods; other foods in which it is used near the maximum level are imitation dairy products, 0.39, and confectionary frostings, 0.38% (wtd. mean), respectively.

CHEMICAL INFORMATION

I. Nomenclature

This monograph is primarily about food grade lecithins which are predominantly soybean lecithin and its modified forms.

A. Common names:

Lecithin

Modified Lecithin, Hydrogen Peroxide modified

Modified Lecithin, Benzoyl Peroxide modified

B. Chemical Names:

Lecithin (Phosphatidic acid monoester with choline)

Phosphatidyl choline

Modified lecithins: No information

C. Synonyms:

Lecithin: Lecithol; Vitellin; Kelecin; Granulestin; Phospholuteins

Modified lecithins: No information

Note: Lecithin terminology is slightly confusing.

In industrial circles, the terms lecithin and soybean lecithin are used for the phosphatide residue which is a byproduct of the manufacture of soybean oil. The terms "Phosphatides" and "Soybean Phosphatides" are used to denote oil-free soybean lecithin. The terms commercial lecithin and lecithin, today are applied almost exclusively to soybean lecithin. Soybean lecithin contains cephalins as well as lecithins. Single-bleached lecithin is bleached with hydrogen peroxide (modified Lecithin, Hydrogen Peroxide modified). Double-bleached lecithin is first bleached with hydrogen peroxide and then further bleached with benzoyl peroxide (1549). (See this Section, VI, Description, for further details.)

D. Trade Names: No information

E. Chemical Abstracts Services Unique Registry Number:

Lecithin	MX8002435
Modified Lecithin Benzoyl Peroxide modified	Not available
Modified Lecithin Hydrogen Peroxide modified	Not available

II. Empirical Formula

A. Lecithin

Not known

B. Benzoyl peroxide modified lecithin

Not known

C. Hydrogen peroxide modified lecithin

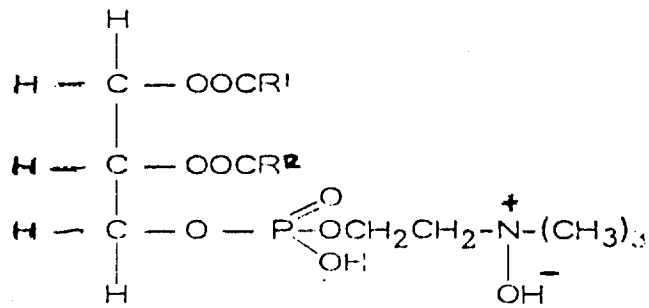
Not known

III. Structural Formula

Lecithin

The lecithins are members of a group of naturally occurring substances called Phosphatides (Phospholipids) which are composed of glycerophosphoric acid linked to a nitrogenous base and/or a carbohydrate (1549).

Pure lecithin or "true lecithin - Phosphatidyl choline - has the general structural formula (0119, 1132):



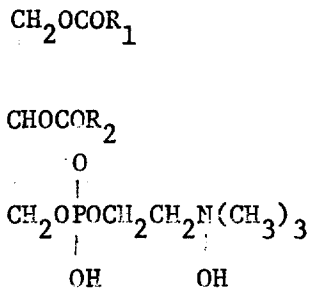
L-α-lecithin (α-Phosphatidyl choline)

R_1 and R_2 are fatty acid groups, saturated and/or unsaturated, such as palmitic, stearic, oleic, linoleic, linolenic, etc. Since R_1 and R_2 can vary, there are a number of lecithins or Phosphatidyl cholines (1550, 2441).

Commercial lecithin is a complex mixture of acetone-insoluble phosphatides (including "true"lecithins) and cephalins (see Table 3) together with other substances such as glyceride oils, fatty acids, sterols, carbohydrates which occur with the phosphatides extracted from vegetable oils and seeds or from animal sources such as egg yolk (2441).

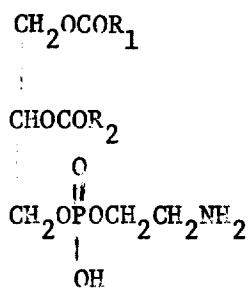
Food grade lecithin is obtained from soybeans (See Figure 1). It is a complex mixture of acetone-insoluble phosphatides composed mainly of phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine and phosphatidyl inositol, combined with other substances such as triglycerides, fatty acids,

and carbohydrates (0563).



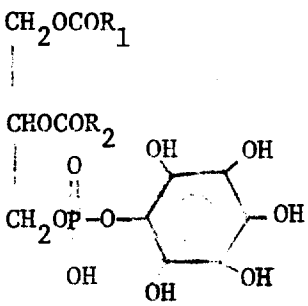
Phosphatidyl choline

I



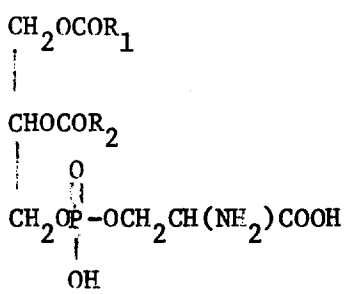
Phosphatidyl ethanolamine

II



Phosphatidyl inositol

III



Phosphatidyl serine

IV

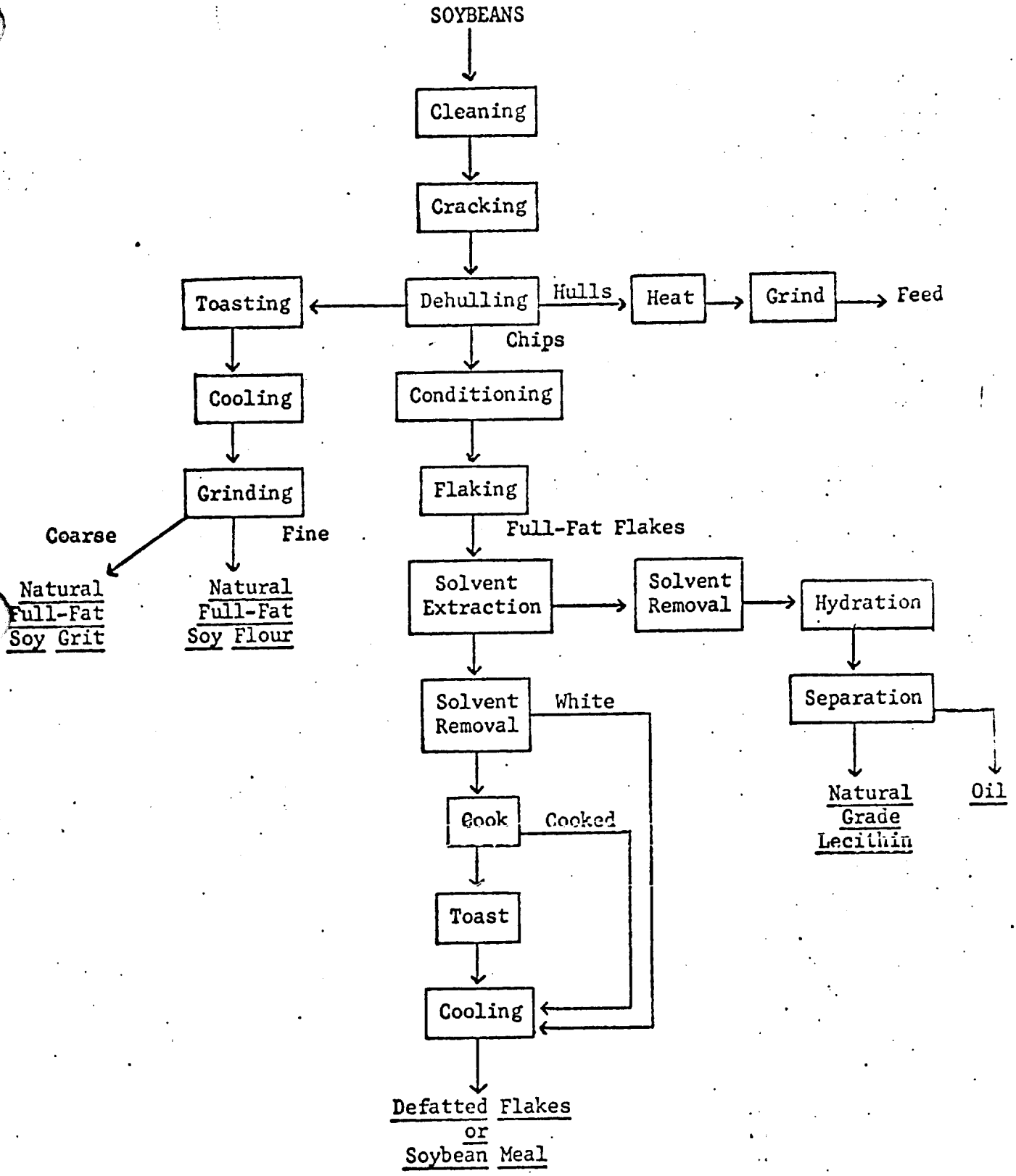
Stanley (2674) includes II, III, and IV above in the "cephalins" category. Scholfield (2487), as well as Stanley (2674), indicates the presence of at least another inositol-containing phosphatide in soybean lecithin, exact structure apparently uncertain (see original articles for details).

Variability in the fatty acid composition of lecithin, as mentioned earlier, is illustrated by the following. According to the Merck Index (2677), soybean lecithin contains palmitic acid 11.7%, stearic 4.0%, palmit-oleic 8.6%, oleic 9.8%, linoleic 55.0%, linolenic 4.0%, C_{20} to C_{22} acids (including arachidonic) 5.5%. Analytical data on soybean lecithin reported by West (2963) were as follows: palmitic acid 15.77%, stearic 6.30%, oleic acid 12.98%, linoleic 62.92%, and linolenic acid 2.02%.

Modified Lecithin, Hydrogen Peroxide modified: No information.

Modified Lecithin, Benzoyl Peroxide modified: No information.

Figure 1. Soybean Processing (0100)



For more information on soybean processing, consult 1549; 1550; 2441; 2674; 2963 of this monograph and the Soybean Oil monograph, Tracor Jitco, Inc., December 27, 1973.

IV. Molecular Weight

Lecithin

Not known

Benzoyl Peroxide modified lecithin

Not known

Hydrogen Peroxide modified lecithin

Not known

V. Specifications

A. Chemical (Lecithin and Modified Lecithins)

Lecithin comes in the following grades: technical; edible (1132); unbleached; single-bleached; double-bleached of plastic consistency as well as fluid consistency (2441).

West (2963) states that the major components of soybean phosphatides are present in almost equal amounts (Table 1).

Table 1. Major Components of Soybean Phosphatides (2963)

Component	Approximate Amount
Phosphatidyl cholines - lecithin	29%
Phosphatidyl ethanolamines Phosphatidyl serines (small amt.)	29%
Inositol-containing Phosphatides	31%

Ingleton (1256) gives the following analysis of soybean lecithin:

Table 2. Composition of Commercial Lecithin Derived from Soyabeans (1256)

Component	Amount %
Phosphatidylcholine & lysophosphatidyl choline	20
Phosphatidylethanolamine & lysophosphatidyl ethanolamine	18
Phosphornositol	10
Phosphatidyl serine & lysophosphatidyl serine	3
Other phosphorus-containing components and phosphatides	10
Soyabean oil	39

More detailed analytical data on commercial soybean lecithin and lecithin fractions, according to Sartoretto (2441) are given in Tables 3 and 4.

Table 3. Chemical Composition of Commercial Soybean Lecithin (7a) (2441)

soybean oil, %	35	tocopherol, mg/g	1.3
lecithin, %	19.7	biotin, μg/g	0.42
cephalin, %	19.7	folic acid, μg/g	0.60
inositol phosphatides, %	21.0	thiamin, μg/g	0.115
carbohydrates (sterol glucoside), %	3.6	riboflavin, μg/g	0.33
moisture and other substances, %	1.0	pantothenic acid, μg/g	5.59
inositol, mg/g	30.0	pyridoxine, μg/g	0.29
choline, mg/g	29.3	niacin, μg/g	0.12

Table 4. Analysis of Lecithin Fractions (2441)

	Oil-free natural lecithin	Alcohol-soluble lecithin	Alcohol-insoluble lecithin
typical composition, %			
chemical lecithin	29.5	60	4
chemical cephalin	29.5	30	28.5
inositol phosphatides	31.6	2.2	55
soybean oil	3.1	4	4
miscellaneous	6.3	3.8	8.5
appearance	granular	soft, waxy solid	granular
color	tan	dark tan to brown	yellow to light tan
solubility			
oil	soluble	soluble	soluble
water	dispersible	dispersible	dispersible
alcohol (warm)	dispersible	soluble	insoluble
taste-odor	refining procedures yield improvements over natural lecithin; these have proved important in some bland food products		
compatibility	ease of incorporation into an emulsion system is influenced by proper selection of carrier		
emulsion type favored	either oil-in-water or water-in-oil	oil-in-water	water-in-oil

Specifications for various grades of commercial lecithins are given in Tables 5, 6, 7, and 8.

Table 5. Types of Soy Lecithin (1549)

Characteristic	Plastic	Fluid
Moisture[a]	1% max	1% max
Insolubles in benzene	0.3% max	0.3% max
Insolubles in acetone	65% max	62% max
Acidity index	30 max	32 max
Viscosity, Poises at 25°C[b]	-	150 max
Penetration[c]	22 mm max	-

[a]By distillation in toluene for 2 hrs. or less (AOCS, Ja 2-56)

[b]By means of a conventional viscometer or by the bubble system and AOCS time, method Ka 6-59, assuming density equal to one.

[c]Using Precision cone 13J25, and Penetometer 3510, sample kept at 25°C for 24 hrs.

Table 6. Tentative Soybean Lecithin Specifications (2441)

Analysis	Grade		
	Fluid natural lecithin	*Fluid bleached lecithin*	*Fluid double-bleached lecithin*
acetone insoluble, % min	62	62	62
moisture,[a] % max	1	1	1
benzene insoluble, % max	0.3	0.3	0.3
acid value, max	32	32	32
color, Gardner,[b] max	10	7	4
viscosity,[c] P at 77°F, max	150	150	150
	Plastic natural lecithin	*Plastic bleached lecithin*	*Plastic double-bleached lecithin*
acetone insoluble, % min	65	65	65
moisture,[a] % max	1	1	1
benzene insoluble, % max	0.3	0.3	0.3
acid value, max	30	30	30
color, Gardner,[b] max	10	7	4
penetration,[d] mm max	22	22	22

[a] By toluene distillation for 2 hr or less (Am. Oil Chemists' Soc. Ja 2-56).

[b] On a 5% solution in mineral oil.

[c] By any appropriate conventional viscosimeter, or by AOCS bubble time method Ka-6-59, assuming density to be unity. Fluid lecithin having a viscosity less than 75 P may be considered a premium grade.

[d] Using precision cone 73525. Penetrometer 73510, sample conditioned 24 hr at 77°F.

Table 7. General Approximate Constants of Commercial Lecithin (2441)

iodine value	95	choline, %	3.0
saponification value	196	ethanolamine, %	0.8
sp gr at 25°C	1.0305	serine or similar amine, %	1.5
pH	6.6	inositol, %	3.0
isoelectric point, pH	3.5	tocopherols, %	0.1
ash, %	7.0	sterols, %	2.0
amino, nitrogen, %	0.4	tartaric acid, %	1.5
galactose, %	3.0	K, Na, Mg, Ca, %	1.0
other carbohydrates, %	5.0		

Table 8. Commercial Lecithin Specifications (3000)

Type	Acetone-insoluble (%)	Phosphorous (%)	Acid number (max.)	Color (Lovibond)* Yellow	Color (Lovibond)* Red	Consistency (penetrometer)	Viscosity (Poises at 80° C.)
Plastic (Non-pourable)							
Minimum Bleach							
Product 1	67	2.2	26	35	2.5	8–12 mm	—
Product 2	65	—	30	30	2.5	8–12 mm	—
Product 3	65–68	2.1–2.9	—	35	10.0**	—	—
Product 4	67	2.25	26	30	2.0	10 mm	—
Product 5	64–68.5	—	—	25	3.0	10 mm	—
Single Bleach							
Product 6	67	2.2	26	35	1.2	8–12 mm	—
Product 7	67	2.3	26	15	0.7	10 mm	—
Product 8	64–68.5	—	—	10	1.0	10 mm	—
Double Bleach							
Product 9	67	2.2	27	3.5	0.8	—	—
Soft (Pourable)							
Minimum Bleach							
Product 10	65	2.1	32	35	2.5	30–40 mm	—
Product 11	62	2.1	32	35	2.5	30–40 mm	—
Product 12	63	2.1	30	30	2.5	—	—
Product 13	61–64	2.0–1.8	—	35	10.0**	—	100–300
Product 14	65	2.1	32	30	2.0	36 mm	—
Product 15	64–68.5	—	—	25	3.0	—	—
Single Bleach							
Product 16	65	2.1	32	30	1.2	30–40 mm	—
Product 17	62–65	1.9–2.1	—	35	7.5**	—	100–300
Product 18	63	—	30	—	1.0	32–40 mm	—
Product 19	65	2.1	32	15	0.7	36 mm	—
Product 20	64–68.5	—	—	10	1.0	—	—
Double Bleach							
Product 21	65	2.2	32	3.5	0.8	30–40 mm	—
Product 22	62–65	1.9–2.1	—	35.0	2.5**	—	100–300
Product 23	62–65	1.9–2.1	—	35.0	2.5**	—	—
Product 24	65	2.1	32	3.5	0.8	36 mm	—
Fluid (Readily Pourable)							
Product 25	59–61	1.9	36	35	2.5	—	—
Product 26	54–57	1.7–1.9	—	35	7.5**	—	30–70

* One per cent solution dissolved in white mineral oil, except where indicated.
** Five per cent solution.

B. Food Grade (Lecithin and Modified Lecithins)

Lecithin

Food Chemicals Codex, second edition, gives the following specifications for food grade lecithin (0563).

Acetone-insoluble matter (phosphatides). Not less than 50.0 percent.

Acid value. Not more than 36.

Benzene-insoluble matter. Not more than 0.3 percent.

Water. Not more than 1.5 percent.

Limits of Impurities

Arsenic (as As). Not more than 3 parts per million (0.0003 percent).

Heavy metals (as Pb). Not more than 40 parts per million (0.004 percent).

Lead. Not more than 10 parts per million (0.001 percent).

TESTS

Acetone-insoluble matter (Phosphatides)

Purification of Phosphatides. Dissolve 5 grams of phosphatides from previous *Acetone insoluble matter* determinations in 10 ml. of petroleum ether, and add 25 ml. of acetone to the solution. Transfer approximately equal portions of the precipitate to each of two 40-ml. centrifuge tubes using additional portions of acetone to facilitate the transfer. Stir thoroughly, dilute to 40 ml. with acetone, stir again, chill for 15 minutes in an ice bath, stir again, and then centrifuge for 5 minutes. Decant the acetone, crush the solids with a stirring rod, refill the tube with acetone, stir, chill, centrifuge, and decant as before. The solids after the second centrifugation require no further purification and may be used for preparing the *Phosphatide-Acetone Solution.* Five grams of the purified phosphatides are required to saturate about 16 liters of acetone.

Phosphatide-Acetone Solution. Add a quantity of purified phosphatides to sufficient acetone, previously cooled to a temperature of about 5°, to form a saturated solution, and maintain the mixture at this temperature for 2 hours, shaking it vigorously at 15-minute intervals. Decant the solution through a rapid filter paper avoiding the transfer of any undissolved solids to the paper and conducting the filtration under refrigerated conditions (not above 5°).

Procedure. If it is plastic or semisolid, soften a portion of the lecithin by warming it in a water bath at a temperature not exceeding 60° and then mixing it thoroughly. Transfer 2 grams of a well-mixed sample, accurately weighed, into a 40-ml. centrifuge tube, previously tared with a glass stirring rod, and add 15 ml. of *Phosphatide-Acetone Solution* from a buret. Warm the mixture in a water bath until the lecithin melts, but avoid evaporation of the acetone. Stir until the sample is completely disintegrated and dispersed, and then transfer the tube into an ice bath, chill for 5 minutes, remove from the ice bath, and add about one-half of the required volume of *Phosphatide-Acetone Solution*, previously chilled for 5 minutes in an ice bath. Stir the mixture to complete dispersion of the sample, dilute to 40 ml. with chilled

Phosphatide-Acetone Solution (5°), again stir and return the tube and contents to the ice bath for 15 minutes. At the end of the 15-minute chilling period stir again while still in the ice bath, remove the stirring rod, temporarily supporting it in a vertical upside-down position, and centrifuge the mixture immediately at about 2000 rpm for 5 minutes. Decant the supernatant liquid from the centrifuge tube, crush the centrifuged solids with the same stirring rod previously used, and refill the tube to the 40-ml. mark with chilled (5°) *Phosphatide-Acetone Solution*, and repeat the chilling, stirring, centrifugation, and decantation procedure previously followed. After the second centrifugation and decantation of the supernatant acetone, again crush the solids with the assigned stirring rod, and place the tube and its contents in a horizontal position at room temperature until the excess acetone has evaporated. Mix the residue again, dry the centrifuge tube and its contents at 105° for 45 minutes in a forced draft oven, cool, and weigh. Calculate the percent of acetone-insoluble substances by the formula $(100R/S) - B$, in which R is the weight of residue, S is the weight of the sample, and B is the percent of *Benzene-insoluble matter* determined as directed in this monograph.

Acid value. If it is plastic or semisolid, soften a portion of the lecithin by warming it in a water bath at a temperature not exceeding 60° and then mix it thoroughly. Transfer about 2 grams of a well-mixed sample into a 250-ml. Erlenmeyer flask and dissolve it in 50 ml. of petroleum ether. To this solution add 50 ml. of alcohol, previously neutralized to phenolphthalein with 0.1 *N* sodium hydroxide, and mix well. Add phenolphthalein T.S. and titrate with 0.1 *N* sodium hydroxide to a pink end-point which persists for 5 seconds. Calculate the number of mg. of potassium hydroxide required to neutralize the acids in 1 gram of the sample by multiplying the number of ml. of 0.1 *N* sodium hydroxide consumed in the titration by 5.6 and dividing the result by the weight of the sample.

Benzene-insoluble matter. If plastic or semisolid, soften a portion of the lecithin by warming it at a temperature not exceeding 60° and then mix it thoroughly. Weigh 10 grams of a previously well-mixed sample into a 250-ml. wide-mouth Erlenmeyer flask, add 100 ml. of benzene, and shake until the lecithin is dissolved. Filter the solution through a 30-ml. Corning "C" porosity or equivalent filtering funnel which previously has been dried at 105° for 1 hour, cooled in a desiccator, and weighed. Wash the flask with two successive 25-ml. portions of benzene and pass the washings through the filter. Dry the funnel at 105° for 1 hour, cool to room temperature in a desiccator, and weigh. From the gain in weight of the funnel calculate the percent of the benzene-insoluble matter in the sample.

Water. Determine by the *Toluene Distillation Method*, page 979, using a 100-gram sample, accurately weighed.

Arsenic. A *Sample Solution* prepared as directed for organic compounds meets the requirements of the *Arsenic Test*, page 865.

Heavy metals. Prepare and test a 500-mg. sample as directed in *Method II* under the *Heavy Metals Test*, page 920, using 20 mcg. of lead ion (Pb) in the control (*Solution A*).

Lead. A *Sample Solution* prepared as directed for organic compounds meets the requirements of the *Lead Limit Test*, page 929, using 10 mcg. of lead ion (Pb) in the control.

Packaging and storage. Store in well-closed containers.

Functional use in foods. Antioxidant; emulsifier.

The Joint FAO/WHO Expert Committee on Food Additives (1305) lists the following specifications:

Loss on drying: Not more than 2.0% at 105°C for 1 hr.

Benzene insolubles: Not more than 0.3%.

Acid value: Not less than 25 and not more than 35.

Peroxide value: Not more than 10 (not applicable to bleached lecithin).

Arsenic: Not more than 3 mg/kg.

Lead: Not more than 10 mg/kg.

Heavy metals: Not more than 40 mg/kg.

VI. Description

A. General Characteristics

Lecithin

Pure lecithin is a white paraffin-like material.

Food grade soya lecithin varies in consistency from plastic to fluid in accordance with the content of free fatty acids and soybean oil and presence or absence of other diluents. The color is light yellow to brown depending on whether it is bleached or unbleached. It is odorless or has a slight nut-like aroma and a bland taste. Food grade diluents (cocoa butter, vegetable oils, etc.) are often used to replace the natural soybean oil to improve functional and flavor characteristics. (See original article for description of refined grades and oil-free forms.) (0563).

Modified Lecithins

Single-bleached lecithin is prepared with hydrogen peroxide to improve color and increase its capacity for emulsification (1549, 3000). A maximum of 2% of 30 to 35% aqueous peroxide is used, based on the phosphatides. The actual concentration used is influenced by the source of the phosphatides and processing conditions (3000). Wittcoff states that "the ease with which any excess hydrogen peroxide decomposes to harmless products makes its use desirable." (3000)

Benzoyl peroxide also is used in bleaching lecithin. It is claimed that the final product has a softer, smoother consistency, among other advantages (1549, 3000). In the manufacture of double-bleached lecithin, 0.1% of hydrogen peroxide

(35%) and 0.008% of dry benzoyl peroxide are used (see original article for details)(1549).

Sodium chlorite and fatty peroxides, such as lauroyl peroxide, also have been suggested as bleaching agents (1549, 3000).

Physical bleaching agents, such as various bleaching clays and activated earths, have been proposed for use in soybean processing (1549, 3000). Processes using acid-activated bleaching clays and alkaline clays to improve color and odor of phosphatides have been patented (3000).

Lajara (1549) mentions a "water dispersible" lecithin produced by addition and mixture of 8 to 10% of an emulsifying agent (not named) and 4 to 5% hexylene glycol to double-bleached fluid lecithin.

The same author (1549) mentions also that the emulsifying properties of lecithin (30-40%) in soy oil can be increased by the addition of propyl gallate and the "stearate of polyoxyethylene" (1549).

B. Physical Properties

Lecithin

Lecithin is readily soluble in most fat solvents but is characteristically insoluble in acetone, soluble in mineral oils and fatty acids but practically insoluble in cold vegetable and animal oils. It is soluble in acetic acid, glycerol, and pyridine also. In water, it swells and forms a cloudy colloidal solution (2677, 3000).

Although the melting point of lecithin is over 200°C, it softens below 100°C. It decomposes above 100°C unless the heating period is very short (2677, 3000).

Modified lecithins: No information.

C. Stability in Containers, etc.

Lecithin

Pure lecithin is extremely hygroscopic and becomes a soft sticky plastic mass in the presence of moisture (3000). It is unstable in air also, like other pure glycero-phosphatides containing unsaturated fatty acids, and starts to oxidize almost as soon as exposed becoming yellow to brown in color and develops a disagreeable odor and taste (2677, 3000). Ashby (0155) found that egg yolk lecithin exposed to air at room temperature became toxic for rabbits. Under high vacuum, however, the substance was stable for seven months. Fischgold

et al. (0850) reported that lecithin in 90% alcohol decomposed even in a desiccator although not as rapidly as when exposed to air. Fatty acids were liberated during the spontaneous decomposition but no choline separation could be detected.

Commercial soybean lecithin, which contains about 33% soybean oil, in contrast to the pure substance is reported to be stable for years under atmospheric conditions (2441). Aylward (0168) states that natural antioxidants present in the commercial grades stabilize both the lecithins and the triglycerides.

Emulsions of lecithins for industrial purposes are susceptible to attack by microorganisms and must be preserved by a suitable germicide during storage (2441).

Lecithins should be stored in well-closed containers protected from light and in a cool place. Phosphatides break down above 40°C (104°F) (1255).

Modified lecithins: No information.

Hydroxylated Lecithin (0563)[a]

Hydroxylated lecithin is derived from a complex mixture of acetone-insoluble phosphatides from soybean and other plant lecithins, consisting chiefly of phosphatidyl choline, phosphatidyl ethanolamine, and phosphatidyl inositol, as well as other minor phospholipids and glycolipids mixed with varying amounts of triglycerides, fatty acids, sterols, and carbohydrates. The mixture is treated with hydrogen peroxide, benzoyl peroxide, and lactic acid to produce a hydroxylated product having an iodine value approximately 10 percent lower than that of the starting material. Hydroxylated lecithin may vary in consistency from fluid to plastic, depending upon the content of free fatty acid and soybean oil and whether or not it contains diluents. It is light yellow in color and has a characteristic "bleached" odor. It is partially soluble in water but hydrates readily to form emulsions; it is more dispersible and hydrates more readily than crude lecithin.

SPECIFICATIONS

Acetone-insoluble matter (phosphatides). Not less than 50 percent.

Acid value. Not more than 70.

Benzene-insoluble matter. Not more than 0.3 percent.

Iodine value. Between 85 and 95.

Peroxide value. Not more than 100.

Water. Not more than 1.5 percent.

[a]Although hydroxylated lecithin is not specifically a subject of this monograph, the data above and others were included because its characteristics are quite similar to lecithin modified with hydrogen peroxide and lecithin modified with benzoyl peroxide (see also BIOCHEMICAL ASPECTS, VI. Consumer Exposure).

Limits of Impurities

Arsenic (as As). Not more than 3 parts per million (0.0003 percent).

Heavy metals (as Pb). Not more than 40 parts per million (0.004 percent).

Lead. Not more than 10 parts per million (0.001 percent).

TESTS

Acetone-insoluble matter (phosphatides)

Purification of Phosphatides. Dissolve 5 grams of phosphatides from previous *Acetone-insoluble matter* determinations in 10 ml. of petroleum ether, and add 25 ml. of acetone to the solution. Transfer approximately equal portions of the precipitate to each of two 40-ml. centrifuge tubes using additional portions of acetone to facilitate the transfer. Stir thoroughly, dilute to 40 ml. with acetone, stir again, chill for 15 minutes in an ice bath, stir again, and then centrifuge for 5 minutes. Decant the acetone, crush the solids with a stirring rod, refill the tube with acetone, stir, chill, centrifuge, and decant as before. The solids after the second centrifugation require no further purification and may be used for preparing the *Phosphatide-Acetone Solution.* Five grams of the purified phosphatides are required to saturate about 16 liters of acetone.

Phosphatide-Acetone Solution. Add a quantity of purified phosphatides to sufficient acetone, previously cooled to a temperature of about 5°, to form a saturated solution, and maintain the mixture at this temperature for 2 hours, shaking it vigorously at 15-minute intervals. Decant the solution through a rapid filter paper avoiding the transfer of any undissolved solids to the paper and conducting the filtration under refrigerated conditions (not above 5°).

Procedure. If it is plastic or semisolid, soften a portion of the sample by warming it in a water bath at a temperature not exceeding 60° and then mixing it thoroughly. Transfer 2 grams of a well-mixed sample, accurately weighed, into a 40-ml. centrifuge tube, previously tared with a glass stirring rod, and add 15 ml. of *Phosphatide-Acetone Solution* from a buret. Warm the mixture in a water bath until the sample melts, but avoid evaporation of the acetone. Stir until the sample is completely disintegrated and dispersed, and then transfer the tube into an ice bath, chill for 5 minutes, remove from the ice bath, and add about one-half of the required volume of *Phosphatide-Acetone Solution*, previously chilled for 5 minutes in an ice bath. Stir the mixture to complete dispersion of the sample, dilute to 40 ml. with chilled *Phosphatide-Acetone Solution* (5°), again stir and return the tube and contents to the ice bath for 15 minutes. At the end of the 15-minute chilling period stir again while still in the ice bath, remove the stirring rod, temporarily supporting it in a vertical upside-down position, and centrifuge the mixture immediately at about 2000 rpm for 5 minutes. Decant the supernatant liquid from the centrifuge tube, crush the centrifuged solids with the same stirring rod previously used, and refill the tube to the 40-ml. mark with chilled (5°) *Phosphatide-Acetone Solution*, and repeat the chilling, stirring, centrifugation, and decantation procedure previously followed. After the second centrifugation and decantation of the supernatant acetone, again crush the solids with the assigned stirring rod, and place the tube and its contents in a horizontal position at room temperature until the excess acetone has

evaporated. Mix the residue again, dry the centrifuge tube and its contents at 105° for 45 minutes in a forced draft oven, cool, and weigh. Calculate the percent of acetone-insoluble matter by the formula $(100R/S) - B$, in which R is the weight of residue, S is the weight of the sample, and B is the percent of *Benzene-insoluble matter* determined as directed in this monograph.

Acid value. If it is plastic or semisolid, soften a portion of the sample by warming it in a water bath at a temperature not exceeding 60° and then mix it thoroughly. Transfer about 2 grams of a well-mixed sample into a 250-ml. Erlenmeyer flask and dissolve it in 50 ml. of petroleum ether. To this solution add 50 ml. of alcohol, previously neutralized to phenolphthalein with 0.1 N sodium hydroxide, and mix well. Add phenolphthalein T.S. and titrate with 0.1 N sodium hydroxide to a pink end-point which persists for 5 seconds. Calculate the number of mg. of potassium hydroxide required to neutralize the acids in 1 gram of the sample by multiplying the number of ml. of 0.1 N sodium hydroxide consumed in the titration by 5.6 and dividing the result by the weight of the sample.

Benzene-insoluble matter. If plastic or semisolid, soften a portion of the sample by warming it at a temperature not exceeding 60° and then mix it thoroughly. Weigh 10 grams of a previously well-mixed sample into a 250-ml. wide-mouth Erlenmeyer flask, add 100 ml. of benzene, and shake until the sample is dissolved. Filter the solution through a 30-ml. Corning "C" porosity or equivalent filtering funnel which previously has been dried at 105° for 1 hour, cooled in a desiccator, and weighed. Wash the flask with two successive 25-ml. portions of benzene and pass the washings through the filter. Dry the funnel at 105° for 1 hour, cool to room temperature in a desiccator, and weigh. From the gain in weight of the funnel calculate the percent of the benzene-insoluble matter in the sample.

Iodine value. Determine by the *Wijs Method*, page 906.

Peroxide value. Weigh accurately about 10 grams of the sample, add 30 ml. of a 3:2 mixture of glacial acetic acid-chloroform, and mix. Add 1 ml. of a saturated solution of potassium iodide, mix, and allow to stand for 10 minutes. Add 100 ml. of water, begin titrating with 0.05 N sodium thiosulfate, adding starch T.S. as the end-point is approached, and continue the titration until the blue starch color has just disappeared. Perform a blank determination (see page 2), and make any necessary correction. Calculate the peroxide value, as mcg. of peroxide per kg. of sample, by the formula $S \times N \times 1000/W$, in which S is the net volume, in ml., of sodium thiosulfate solution required for the sample, N is the exact normality of the sodium thiosulfate solution, and W is the weight, in grams, of the sample taken.

Water. Determine by the *Toluene Distillation Method*, page 979, using a 100-gram sample, accurately weighed.

Arsenic. A *Sample Solution* prepared as directed for organic compounds meets the requirements of the *Arsenic Test*, page 865.

Heavy metals. Prepare and test a 500-mg. sample as directed in *Method II* under the *Heavy Metals Test*, page 920, using 20 mcg. of lead ion (Pb) in the control (*Solution A*).

Lead. A *Sample Solution* prepared as directed for organic compounds meets the requirements of the *Lead Limit Test*, page 929, using 10 mcg. of lead ion (Pb) in the control.

Packaging and storage. Store in well-closed containers.
Functional use in foods. Emulsifier; clouding agent.

VII. Analytical Methods

A. Assay of Lecithin Content

1. Extraction of sample with chloroform-absolute alcohol (1:1) and determination of total P as P_2O_5 (0159).
2. Quantitative determination of acetone-insoluble material in a sample (1305).

B. Analysis of Commercial Lecithin

1. Methods for determination of free fatty acids, moisture, total P, petroleum insoluble material, residual acetone and acetone insoluble material (1237).
2. Rapid volumetric method based on ashing sample, converting P monophosphate and titration with standard uranyl nitrate solution (2674).
3. Semi-micro colorimetric determination of P as a solvent-free extract (2674).
4. Semi-micro spectrophotometric determination of P as a solvent-free extract using a Beckman or Coleman spectrophotometer (2674.

C. Differentiation between Egg and Soybean Lecithin Added to Farinaceous Products

The addition of as little as 0.5 percent soybean lecithin to macaroni and noodle products can be detected by the strong fluorescence of soybean lecithin in u.v. light which is proportional to the concentration present. There is no interference from up to 15 percent added soy flour (2993).

D. Analysis of Phospholipids in Lecithin

Separation by thin-layer chromatography (TLC) followed by quantitative analysis with x-ray emission spectrometry (0488).

E. Phospholipid analysis of tissue blood lymph, milk and fecal matter by the combined use of TLC and gas-liquid chromatography (1520).

VIII. Occurrence and Levels

Lecithin

Lecithins are found in all living organisms, both plant and animal (2677).

A. Plants

In the plant kingdom, all seeds, beans, nuts, grains, and other tissues where oil is present contain lecithin (2673). The amount varies considerably according to the species (1549). Soybeans contain somewhat less than 1% (0473). In general, the amount in seeds seldom exceeds 0.5% (1549). In extracted plant oils, the concentration is higher of course. Soybean oil, for example, yields an average of 2.65% commercial lecithin (2674). The phosphatides content of a number of other plant oils according to Lajara (1549), 1970, are given in Table 9.

Table 9. Phosphatide Content of Some Common Plant Oils (1549)

Oil	Phosphatides, %
Cotton	0.7-0.9
Rice	0.5
Oat	1.0
Peanut	0.3-0.4
Barley	3.4-4.2
Rye	1.3-4.0
Rape (Colza)[a]	0.1
Linseed	0.3
Corn	1.0-2.0
Millet	0.2
Sesame	0.1
Soy	1.1-3.2
Wheat	0.08-2.0

[a]Stanley (2674) reports an average of 1.33% for Rape seed oil. Lajara (1549) points out that lecithin percentages vary considerably not only according to the species but also for the same material according to the method of extraction.

The amount of lecithin in the soybean phosphatides fraction ranges from 30 to 35% (2487). Peanut and sunflower seed phosphatides contain 35.7% and 38.5%, respectively (1549). Alcohol-ether extracts of beans (type not mentioned), peas, and lupines assayed over 50% lecithin in some cases (2441).

B. Animals

The phosphatides are important components of every living cell. Egg yolk contains about 10% lecithin (0168). Brain and nerve tissue (7%), the liver (9%), and kidneys (5.6%) are rich in lecithin (2963). Concentrations in the other organs are given in Table 10. The levels in blood and the blood cells are presented in Table 11. Whole milk contains 0.035-0.036% "lecithin" (1144).

Table 10. Lecithin, etc. Content of Various Beef Organs (2963)

Organ	Total Phosphatide	Lecithins	Cephalins	Sphingomyelins[a]
Brain	26.37	7.05	14.35	4.96
Liver	16.22	8.86	6.59	0.76
Kidney	10.32	5.62	3.02	1.66
Heart	9.83	3.96	5.34	0.52
Lung	9.78	3.60	3.90	2.27
Thymus	6.71	3.28	2.72	0.70
Muscle	3.24	1.84	1.19	0.20
Egg, chicken	13.73	9.95	3.44	0.34

[a]Results are on the basis of percent of dry weight of the organ for all substances in table.

Table 11. Phosphatides Content of Human Blood (2963)

Serum, plasma or corpuscle	Total Phosphatides mg %	Lecithins* % of total	Cephalins** % of total	Sphingomyelins % of total	Dietary State of Subjects
Serum (6)	226	47	42	11	Postabsorptive
Serum (12)	185		22		Postabsorptive
Serum (2)	229	60	27	13	Not stated
Plasma (4)	189	52	29	19	Not stated
Plasma (unknown no.)	204	61	22	17	Not stated
Plasma (16)	152		20		Postabsorptive
Plasma (20)	145	13	47	40	Fasting
Plasma (11)	235		3***		Postabsorptive
Plasma (unknown no.)	153	55	28	12	Not stated
Serum (2)	184		59		Not stated
Erythrocytes (4)	317	24	60	50	Not stated
Erythrocytes (20)	196	16	60	24	Fasting
Erythrocyte stroma (4)	10	20	50	30	Not stated
Leucocytes (22)	844±241				Not stated

*Phosphatidyl cholines.

**Phosphatidyl ethanolamines chiefly, with some phosphatidyl serines, and inositol phosphatides if present.

***The low values for cephalins, 3 percent of total, obtained by Chaikoff and associates is noteworthy (see original article for details).

C. Synthetics

Soybean lecithin is widely used in industries other than the food industry for its "colloidal, interface-active, emulsifying, softening, detersive, antioxidant, and physiological properties" (see Tables 12 & 13). The many uses of lecithin in the food industry are given in Biochemical Aspects, VI, Consumer Exposure.

Table 12. Industrial Uses of Lecithins (Other than Food) (2441)

Product	Function(s)
Pharmaceuticals	Supply choline, inositol, small amounts of tocopherols and biotin. Lipotropic effect in treatment of hypercholesterolemia, arteriosclerosis, etc. Prevents fatty degeneration of the liver. Better utilization of fat-soluble vitamins.
Soaps & Cosmetics (skin creams, shampoos, hair tonics, massage oil, lipsticks, petroleum jelly, brushless shave cream, etc.)	Emulsifying, penetrating, and emollient agent; antioxidant.
Resins	Blending agent.
Paints, Laquers, Printing Inks	Interfacial dispersing agent.
Plastics	Mold release agent.
Rubber (natural, synthetic, reclaimed)	Accelerator in processing; increases tearing strength and hardness.
Leather	Tanning.
Petroleum Products Lubricating Oils	Reduces bearing corrosion; improves detergency; counteracts sludge, varnish, acid formation; prevents carbon deposit.
Gasoline	Antioxidant; inhibits gum formation; prevents corrosion and rust; de-icer.
Textiles	Emulsifier, penetrant, spreading agent, antioxidant in textile lubricants and softeners. Scouring, degumming, mercurizing, dyeing, printing, bleaching, finishing, etc.

BRIEF SUMMARY AND GUIDE TO SOME LECITHIN USES (0472)

USES	TYPICAL ACTION	SUGGESTED CONCENTRATION	RESULTS AND REMARKS
Animal Feeds (other than pet foods)	Emulsifier, wetting agent	Approx. 1 to 3%	Promotes and stabilizes emulsions. Provides instant wetting of powdered formulations.
Baking	Modify the gluten characteristics of flour, emulsifier, antioxidant, wetting agent.	0.1 to 0.3% based on flour in bread. 1/2 to 1% based on shortening in pies.	Improve the "shortening effect;" reduce emulsifier cost; benefit flavor, shelf-life, texture and moisture retention.
Cake Mixes	See Baking	1 to 3% based on shortening in cakes plus other emulsifiers.	Same as in baking. Also, allows rapid wetting with milk or water. Generally used in combination with monoglycerides.
Candy	Emulsifier	Approx. 1% based on shortening.	Used in fat-containing candy, e.g., caramels, brittle, nougats, and taffies. Aids mixing of sugar, fat, and water to prevent greasiness, graining, and streaking.
Chocolate	Reduces viscosity by wetting and dispersing action.	0.3 to 0.5%	More effective and lower priced than cocoa butter. The higher level may be used to improve moisture tolerance as in ice cream coatings, etc.
Cosmetics	Emulsifier, foam stabilizer, emollient, penetrant, vitamin source, hydrolysis inhibition.	1 to 5%	Normal skin contains about 0.4% lecithin. Natural lecithin contains pantothenic acid, thiamin, folic acid, riboflavin, pyridoxine, biotin and niacin, as well as considerable amounts of inositol and choline.

Table 13

Table 13 (continued)

USES	TYPICAL ACTION	SUGGESTED CONCENTRATION	RESULTS AND REMARKS
Drugs	Emulsifier, suspending agent		CENTROPHIL S is one of few sources for emulsifiers acceptable for use with oils for intravenous injection. Since unadulterated lecithin is nontoxic, other grades find many uses.
Dyes	Solubilizer, dispersing agent	1/4 to 1% on dry weight of dye.	Water soluble food dyes can be solubilized in oil. Also useful in varnishes and lacquers.
Ice Cream		0.001 to 0.1% of final weight	Improves smoothness, prevents "sandiness" on storage; aids dispersion of chocolate. Reduces use of egg yolk and stabilizes fat.
Instant Foods	Wetting, dispersing, emulsifying	1/2 to 3%	Aids reconstitution by improving wettability and dispersion of solids and fats (i.e., dry beverage mixes, etc.).
Insecticide	Oil soluble emulsifier, dispersant		Used alone or blended with other surfactants.
Inks	Grinding aid, solubilizes dyes	1/2 to 2% (See Remarks)	Allows increased pigmentation and modifies flow properties. Optimum amounts depend on formulation. Usual concentration is 1/2% of pigment weight, although up to 2% may be required for difficult pigments.
Leather	Softening agent, oil penetrant	1% of oil	Added to fat liquor.

Table 13 (continued)

USES	TYPICAL ACTION	SUGGESTED CONCENTRATION	RESULTS AND REMARKS
Latex emulsions	Facilitate pigment dispersion; anti-settling agent; prevent agglomeration; emulsion stabilizer; minimize foaming; easy, uniform application without lap marks; freeze-thaw stability.	1 to 5% of the pigment weight	Also see under "Paints." Water dispersible grades of lecithins give best results.
Paints	Aids pigment grinding and dispersion, retards settling, yields maximum color strength and full hiding power.	1/2 to 2%	Pigmentation has been increased as much as 25%. Vehicles assisted include: alkyds, styrenated alkyds, bodied linseed oils, varnishes, lacquers, and natural oils. Pigments assisted include: lithopones, titanium dioxide, zinc sulfide, basic carbonate, white lead, and a variety of reds, blues, yellows, greens, and carbon black. Generally used at 1/2% of pigment weight but up to 2% may be required in some cases.
Pet Foods	Emulsifier, release agent	Approx. 1%	Aids blending of fats and water. Gives clean release from equipment and can.
	Nutrition supplement	3 to 5%	Improved disposition, activity stimulant, associated with glossy fur, aids digestion, and/or increases the efficiency of nutrient assimilation.
Petroleum products	Emulsifier and wetting agent for marine greases, cutting oils, etc.	1/2 to 3%	Improves wettability and stabilizes emulsions and dispersions.
	Multipurpose additive for motor fuel	50 PPM	Maintains clean carburetor conditions, reducing carburetor icing.

Table 13 (continued)

USES	TYPICAL ACTION	SUGGESTED CONCENTRATION	RESULTS AND REMARKS
Plastics	Slip agent, mold release, pigment dispersant	(See Remarks)	May be used either on mold or included in formula. Where part of formula, suggested concentration is 1%. See "Paints" for pigment dispersion information.
Margarine	W/O emulsifier, antispattering agent, browning agent	0.15 to 0.5% (See Remarks)	Concentration depends on degree of emulsion stability desired and grade of lecithin used.
Rubber	Pigment dispersant, mold release agent		See "Plastics"
Shortening	Emulsifier, dispersant	0.5 to 1%	Produces a more complete and uniform blending of the shortening. Increases the shortening action.
Textiles	Softening agent, lubricant		Concentrations depend upon the application or specific properties desired.

The foregoing summary of Lecithin uses is meant merely as a guide to the broad scope of utility. Many other uses have been reported in the technical literature.

Central Soya, Chemurgy Division
Chicago, Illinois
Data from FDA, Exhibit 6

D. Natural Inorganic Sources

None

Modified Lecithins

Hydrogen peroxide modified lecithin and benzoyl peroxide modified lecithin do not occur naturally in plants or in animals. No definite specific information was found on their use in synthetics. There are no natural inorganic sources.

BIOLOGICAL DATA

I. Acute Toxicity

No information on the acute toxicity of lecithins has been found in the literature. For acute toxicity data on soybean oil both the source and a component of commercial lecithin, cf. the GRAS monograph on soybean oil.

II. Short-term Studies

A. Cats

In 1949, Geyer et al. (0968) investigated the vasodepressor activity of soybean phosphatides used in fat emulsions for i.v. nutritional purposes. A species variation with respect to this vasodepressor action was observed. There was none in the rat or rabbit and little in the dog, but the cat, like man, was found to be susceptible.

The results of experiments in which both various soybean phosphatide preparations and various fractions made from commercial soybean phosphatides (asolectin) were injected via a glass cannula into the femoral vein of cats (no specifications given) are shown in Table 14 and Table15 .

A study of other routes of administration with a depressor phosphatide fraction showed that when administered i.p., there was a pressor response and there was no effect with p.o., i.m., or s.c. administration.

The authors noted that the vasodepressor activity observed when commercial soybean phosphatides were administered i.v. to cats must be formed sometime after manufacture by oxidative or degradative changes since freshly prepared soybean phosphatides were found to possess little such activity.

B. Dogs

In 1944, Davis (0633) investigated whether the prolonged daily administration of lecithin would depress the red cell count in normal dogs.

After control determinations of red cell counts and hemoglobin percentages, four normal dogs were fed 5 g commercial lecithin daily along with a diet of Purina chow and rolled oats. Their red cell count is shown in Figure 2.

It can be seen that the erythrocyte numbers were gradually reduced after a latent period of five or more days. After 15 to 25 days of lecithin feeding maximum diminutions of 15 to 25% were reached. All dogs returned to normal within 11 to 20 days following cessation of lecithin feeding.

Table 14. Effect of Various Soybean Phosphatide Preparations on the Blood Pressure of the Cat. (0968)

No.	Material	% of Phosphatide Fraction (wt/vol)	Volume Injected (ml)	Cat No.	Cat Wt (kg)	Blood Pressure Decrease (mm)	Response* Increase (mm)
1	Freshly prepared soybean phosphatides	1.5	0.8	1	0.97	-	10
2	No. 1 autoclaved for 15 min at 15 p.s.i.	1.5	0.8	1	0.97	-	18
3	No. 1 allowed to stand in air at room temp. for 4 days	3.0	0.4	1	0.97	24	-
4	No. 1 + 15% corn oil as an emulsion	2.0	0.5	2	2.30	6	-
5	Liquid lecithin	6.0	0.5	3	0.67	10	-
6	Asolectin	6.0	0.1	4	1.60	28	-
7	Fraction B(F-2) + 15% coconut oil as an emul- Emulsion 35	3.0	0.4	5	2.00	50	-
8	Fraction B(F-2)	3.0	0.4	5	2.00	46	-
9	Fraction B(F-2):	6.0	1.0	8	1.60		
	First injection					77	-
	Second injection (16 min. after first injection)†					18	-
	Third injection (18 min. after first injection) +					10	-

* Refers only to the initial response.

† In each case the blood pressure had returned to normal prior to the injection.

Table 15. Effect of Various Fractions Made from Commercial Soybean Phosphatides (Asolectin) on the Blood Pressure of the Cat. (0968)

NO.	FRACTION	RELATIVE EMULSIFYING PROPERTIES*	CHOLINE CONTENT	CONCENTRATION PER CENT (WT./VOL.)	VOLUME INJECTED (ML.)	CAT		BLOOD PRESSURE RESPONSE	
						NO.	WT. (KG.)	DECREASE (MM.)	INCREASE (MM.)
1	A(F-1)	Poor	—	3.0	1.0	7	2.2	—	6
2	B(F-1)	Fair	0.76	3.0	0.4	7	2.2	6	—
3	C(F-1)	Very good	10.5	3.0	1.0	7	2.2	—	4
4	D(F-1)	Fair	1.85	3.0	0.4	7	2.2	6	—
5	E(F-1)	Fair	0.04	3.0	0.2	7	2.2	54	—
6	B(F-2)	Good	—	3.0	0.3	6	1.5	56	—
7	Lipositol	Poor	—	3.0	1.0	7	2.2	60	—
8	Lipositol-free residue	Fair	—	3.0	1.0	7	2.2	55	—
9	70-f	—	—	1.2	0.1	6	1.5	46	—

*Based on the rating of "good" for fraction B(F-2).

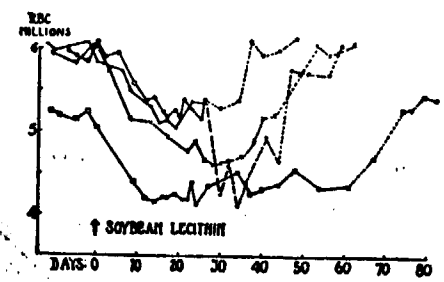


Figure 2. The effect of soybean lecithin on the red blood cell counts of four normal dogs. Dashes indicate cessation of lecithin administration. Long dashes in solid dot line indicate period during which 60 grams of lard was fed daily, in addition to the lecithin (5 grams daily). (0633)

The author concluded that since he found that a daily oral dose of 8 mg/kg BW choline HCl also significantly depressed the erythrocyte number, the lowering of erythrocyte count by soybean lecithin was probably due to its approximately 3% choline content.

C. Calves

In 1961, Roy et al. (2377) investigated the effect of substituting soya lecithin for mechanical homogenization in the diet of newborn calves. Three experiments using 90 newborn bull calves during the first three weeks of life were carried out to study the effect of including soya bean lecithin on a milk substitute diet based on margarine and spray-dried skim milk powder. Experiment 1 compared a crude and a pharmaceutical grade of soya bean lecithin. Experiments 2 and 3 compared mechanical homogenization of margarine fat with emulsification with lecithin.

The results are shown in Tables 16, 17, 18, 19 and 20. The results showed that:

(1) In experiment 1, lecithin in a soya bean oil carrier added to a homogenized diet was found to be superior in producing a live-weight gain over supplementation with a pharmaceutical grade of lecithin.

(2) In experiment 2, emulsification with lecithin was not found to be advantageous over homogenization.

(3) In experiment 3, incorporation of margarine and lecithin was found to be inferior to incorporation of fat by homogenization.

The authors concluded that for liquid diets for newborn calves based on dried skim milk and containing 2% fat, mechanical homogenization is preferable to emulsification with lecithin.

D. Humans

1. In 1944, Steiner and Domanski (2693) found no untoward symptoms or signs during a six-week period during which 8 patients were fed 25 g of "soya lecithin" daily (composition: lecithin 20%, cephalin 20%, oil 30%, phytosterols 2%, inositol and allied compounds 15% and carbohydrates 10%). The serum cholesterol level in each of these patients was significantly lowered for five weeks of the eight week feeding period without an associated increase in basal metabolism.

Table 16. Expt I. Comparison of the Performance (Mean Values with Their Standard Errors) of Calves Given Homogenized Milk-Substitute Diets Containing Two Different Preparations of Soya-bean Lecithin (2377)

	Treatment No. and Details			
	1 No Lecithin	2 Granular Lecithin (95% phosphatides)	3 Lecithin in Soya-bean Oil Carrier (65% phosphatides)	Significance of Difference Between Treatmei
No. of Calves	6	6	6	-
Birth Weight (lb)	84.0 ± 3.51	82.7 ± 3.51	75.0 ± 3.51	-
Total Milk Consumption (pints)	164.5 ± 4.42	156.5 ± 4.42	155.1 ± 4.42	-
Live-weight Gain/Day (lb)	0.77± 0.073	0.57± 0.073	0.74± 0.073	-
No. of Days on Which Calves Scoured	0 (range 0-1)	2 (range 0-6)	1 (range 0-3)	-
Dry Matter in Faeces (%)	23.0 ± 1.0	20.0 ± 1.0	22.0 ± 1.0	-
No. of Days on Which Calves Had a High Rectal Temp (>102·8°F)	0 (range 0-2)	1 (range 0-2)	3 (range 0-7)	3 > 1*
Adjusted Live-weight Gain/Day (lb)†	0.67± 0.041	0.64± 0.039	0.76± 0.037	3 > 1+2*T

* Significant at 0.01 < P < 0.05.

† Adjusted for differences between treatment groups in mean milk consumption and incidence of scouring.

T Overall mean value for treatments 1 and 2.

Table 17. Expt I. Comparison of Levels of Blood Plasma Lipids and Vitamin A (Mean Values with Their Standard Erros) of Calves Given Homogenized Milk-Substitute Diets Containing Two Different Preparations of Soya-bean Lecithin. (2377)

	Treatment No. and Details				
	1 No Lecithin	2 Granular Lecithin (95% phosphatides)	3 Lecithin in Soya-bean Oil Carrier (65% phosphatides)	Pooled Standard Error of Means	Significance of Difference Between Treatments
No. of Calves	6	6	6		
Food Plasma Vitamin A (mg 100 ml):					
At birth	3.8 ± 0.67	3.5 ± 0.67	3.5 ± 0.76†		-
At 4 days	8.4	7.3	8.3	± 1.21	-
At 12 days	7.6	6.1	7.3	± 0.70	-
At 21 days	9.3	8.6	6.9	± 1.01	-
Increase, 4th-21st day	+ 1.0	+ 1.4	- 1.4	± 0.70	3 < 1*, 3 < 2*
Food Plasma Lipids (mg 100 ml):					
At birth	68	101	107	±13.0	1 < 2+3*T
At 4 days	182	157	196	±22.5	-
At 12 days	277	245	284	±36.4	-
At 21 days	324	329	280	±40.2	-

* Significant at 0.01 < P < 0.05.

† One sample not analysed. Missing value calculated by the missing-plot technique of Yates (1933).

T Overall mean value for treatments 2 and 3.

Table 18. Expt 2. Comparison of the Performance (Mean Values with Their Standard Errors) of Calves Given Milk-Substitute Diets Containing Margarine Fat Incorporated by Different Methods.(2377)

	Treatment no. and details				
	4 Homogenization	5 Lecithin + homogenization	6 Lecithin	7 No lecithin or homogenization	Significance of difference between treatments
No. of calves	12	12	12	12	
Birth weight (lb)	75·5 ± 2·99	72·5 ± 2·99	76·2 ± 2·99	80·7 ± 2·99	—
Total milk consumption (pints)	146·6 ± 3·16	142·8 ± 3·16	140·3 ± 3·16	147·1 ± 3·16	—
Live-weight gain/day (lb)	0·58 ± 0·054	0·57 ± 0·054	0·32 ± 0·054	0·22 ± 0·054	5 > 6**, 5 > 7***, 4 > 6**, 4 > 7***, 4+5 > 6+7***†
No. of days on which calves scoured	3 (range 0–6)	2 (range 0–7)	2 (range 0–10)	3 (range 0–9)	—
Dry matter in faeces (%)	19 ± 0·5	20 ± 0·5	19 ± 0·5	17 ± 0·5	4+5 > 6+7*†, 5+6 > 4+7*†, 4 > 7*, 5 > 7**, 6 > 7*
No. of days on which calves had a high rectal temperature (> 102·8 °F)	1 (range 0–7)	2 (range 0–10)	2 (range 0–6)	1 (range 0–4)	—
Adjusted live-weight gain/day (lb)‡	0·55 ± 0·048	0·54 ± 0·049	0·36 ± 0·048	0·24 ± 0·049	4 > 7***, 5 > 7***, 4 > 6*, 5 > 6*

* Significant at $0·01 < P < 0·05$.
** Significant at $0·001 < P < 0·01$.
*** Significant at $P < 0·001$.

† Two treatment nos. joined by a plus sign indicate the mean value of those treatments.
‡ Adjusted for differences between treatment groups in mean birth weight and milk consumption.

Table 19. Expt 2. Comparison of Levels of Blood Plasma Lipids and Vitamin A (Mean Values with Their Standard Errors) of Calves Given Milk-Substitute Diets Containing Margarine Fat Incorporated by Different Methods.(2377)

	Treatment no. and details				Pooled standard error of means	Significance of difference between treatments
	4 Homogenization	5 Lecithin and homogenization	6 Lecithin	7 No lecithin or homogenization		
No. of calves	12	12	12	12		
Blood plasma vitamin A (μg/100 ml):						
At birth	3·3	5·0	4·1	3·7	±0·50	—
At 4 days	6·0	5·9	5·2	6·4	±0·47	—
At 12 days	5·2	5·0	5·2	4·4	±0·39	—
At 21 days	5·8±0·49	5·7±0·54†	5·7±0·49	4·6±0·49	—	—
Increase, birth–4 days	+2·7	+0·9	+1·1	+2·7	±0·44	4+7 > 5+6***§
Adjusted increase, birth–4 days‡	+2·4±0·39	+1·3±0·40	+1·1±0·38	+2·6±0·38	—	{4+7 > 5+6**§, 4 > 6*, 7 > 5*, 7 > 6**
Regression coefficient of increase in plasma vitamin A from birth to 4 days on birth value, −0·4454±0·1316**						
Blood plasma lipids (mg/100 ml):						
At birth	168	145	146	183	±26·7	—
At 4 days	195	222	180	148	±21·8	4+5 > 6+7*§
At 12 days	242	286	188	185	±29·2	4+5 > 6+7*§
At 21 days	315±21·5	265±23·6†	304±21·5	247±21·5	—	4+6 > 5+7*§
Increase, birth–4 days	+27	+77	+34	−35	±33·7	—
Adjusted increase, birth–4 days‡	+35±22·2	+63±22·2	+21±22·2	−13±22·4	—	5 > 7*
Regression coefficient of increase in plasma lipids from birth to 4 days on birth value, −0·9618±0·1441***						

* Significant at $0·01 < P < 0·05$.
** Significant at $0·001 < P < 0·01$.
*** Significant at $P < 0·001$.

† One sample not analysed. Missing value calculated by the missing-plot technique of Yates (1933).
‡ Adjusted for differences between treatments in mean birth value.
§ Two treatment nos. joined by a plus sign indicate the mean value of those treatments.

Table 20. Expt 3. Comparison of the Performance (Mean Values with Their Standard Errors) of Calves Given Milk-Substitute Diets Containing Margarine Fat Incorporated Either by Homogenization into Reconstituted Skim-Milk Powder or Together with Lecithin Directly into the Dry Powder (2377)

	Treatment no. and details		Significance of difference between treatments
	8 Homogenization	9 Lecithin	
No. of calves	12	11	
Birth weight (lb)	81·3 ± 2·74	83·7 ± 2·98†	—
Total milk consumption (pints)	149·7 ± 1·91	152·2 ± 2·08†	—
Live-weight gain/day (lb)	0·49 ± 0·055	0·35 ± 0·060†	—
No. of days on which calves scoured	3 (range 1–7)	3 (range 0–5)	—
No. of days on which calves had a high rectal temperature (> 102·8 °F)	1 (range 0–5)	2 (range 0–6)	—
Adjusted live-weight gain/day (lb)‡	0·48 ± 0·033	0·36 ± 0·036†	8 > 9*

* Significant at $0·01 < P < 0·05$.
† Missing value calculated by the missing-plot technique of Yates (1933).
‡ Adjusted for differences between treatment groups in mean birth weight and milk consumption.

2. In 1949, Geyer et al. (0968) observed in their studies of the vasodepressor activities of soybean phosphatides that man is more sensitive to the vasodepressor action of these phosphatides than the rat, rabbit or dog, but less so than the cat (see this Section A).

3. The Merck Index (2677) also notes that "commercial grades of natural lecithin are reported to contain a potent vasodepressor substance."

4. In 1964, the FAO/WHO (1305) reported the following short-term studies (references given in report):

(1) No untoward reactions were reported when lecithin was administered daily in doses from 22 to 83 g for two to four months.

(2) Doses of 25 to 40 g daily for several months lowered the serum cholesterol level but were not well tolerated.

5. In 1973, Tompkins et al. (2809) studied the effects of chronic administration of phospholipids to humans with gallstone disease over a period of one year. Six patients were first put on a basic low fat diet for two months, then 48 g of commercial soybean lecithin was added to their diet.

It was observed that serum cholesterol and triglycerides were lowered and that patients who had abnormal lipoprotein electrophoreses returned to normal. No renal, hepatic or cardiovascular changes occurred during the study. The authors concluded that their data, demonstrated that the long-term ingestion of large amounts of soybean lecithin is well-tolerated (see also Biological Data IV, E).

III. Long-term Studies

No long-term studies using commercial soybean lecithin were found in the literature.

IV. Special Studies

A. Mice

1. In 1969, Altman et al. (0071) showed that when Swiss mice (20 per group) were administered s.c. soybean phosphatide (Asolectin) along with the carcinogen, methylcholanthrene, the appearance of tumors was retarded. Cholesterol showed a pronounced accelerating activity. The experiment is summarized in Table21 .

TABLE 21. Appearance of tumour after subcutaneous McCadministration (0071)

Group \ Weeks	7 a/b/c	10 a/b/c	12 a/b/c	16 a/b/c	25 a/b/c	30 a/b/c
I (Contr.)	18/4/0	18/7/0	18/9/0	14/10/4	3/2/15	1/0/17
II (PL, once only)	20/2/0	20/2/0	20/3/0	19/10/1	3/0/17	3/0/17
III (PL, oral)	14/0/0	14/4/0	14/5/0	14/10/0	2/1/13	1/0/14
IV (PL, s. c.)	18/1/0	18/2/0	18/4/0	18/11/0	4/2/14	2/0/16
V (PL, i. p.)	18/2/0	18/3/0	18/5/0	14/12/4	1/1/17	0/0/18
VI (PL, i. v.)	9/6/0	8/3/1	8/5/1	4/4/4	0/0/8	—
VII (Chol, once)	19/12/0	19/17/0	18/16/1	8/8/11	0/0/18	—
VIII (Chol, oral)	20/7/0	20/15/0	20/18/0	0/0/20	—	—
IX (Chol, s. c.)	19/7/0	19/15/0	19/18/0	0/0/19	—	—
X (Chol, i. p.)	16/7/0	16/13/0	15/14/1	0/0/16	—	—
XI (Chol, i. v.)	2/0/0	suspended				

must have suffered from the received subcutaneous and intraperitoneal injections for a large excess of unabsorbed PL-emulsion, respectively oil-solutions of Chol, was constantly found either subcutaneously or in the abdominal cavity.

A high mortality was observed in the intravenously injected mice, probably as a consequence of the imperfect condition of the introduced emulsions due to lack of an adequate stabilizer which, in the meantime, has been found in Pluronic F-68, a non-ionic, water-soluble polyoxyethyleneoxypropylene polymer produced by Wyandotte Chemical Corp., Wyandotte, USA [3].

It seems worth while to repeat the introduction of either PL or Chol directly in the bloodstream for the excess of these lipids when administered by other ways has not shown the slightest effect, probably due to metabolic modifications of their molecular structures. However it may be, it must be concluded from the above that the activity of PL and Chol is only perceptible when these compounds find themselves in direct molecular contact with the carcinogen. This confirms the assumed existence of molecular associations of PL and MeC from which MeC can be released by Chol, due to the higher affinity of the latter to PL (see the equation given in the Introduction). As was already explained before [1], PL-MeC associations are too large in size for occupying open spaces in the cell-membranes (cf. ALTMAN [4, 5]).

Experiments are now in progress to verify the activity of a large excess of PL and Chol introduced *together* with the carcinogenic hydrocarbon. At the same time the influence of an excess of these lipids administered intravenously in the form of perfect emulsions is studied.

Thanks are due to V. C. DO AMARAL for his invaluable technical assistance.

[3] P. E. SCHURR, Cancer Res. 29, 258 [1969].

[4] R. F. A. ALTMAN, Arch. Geschwulstforsch. 19, 1, 97 [1962].

[5] R. F. A. ALTMAN, O Hospital [Rio de Janeiro] 73, 1525 [1968].

B. Rats

In 1956, Sergeeva (2522) reported on the effect of orally administered lecithin on the conditioned reflex activity of rats. This experiment was prompted by previous studies referred to in the original article which had shown that lecithin caused significant alterations in the activity of the central nervous system. The author and coworker had also shown that lecithin exerted a considerable effect on the conditioned reflex activity of the cerebral cortex of dogs.

The present experiment used the method of defensive conditioned reflexes (electrostimulation in a 3-chamber passage). The irritability threshold and electroencephelograms of 24 rats were first determined and the animals divided into three groups, with eight in each (two experimental and one control). All were fed a food mixture. In addition one group received 1 mg/200 g BW and the other 25 mg/200 g BW p.o. daily for a total test period of 40 days.

The results showed that the small dose of lecithin increased the brain excitability and the large dose decreased it. There was no change in the conditioned reflex response of controls throughout the test period. The author concluded that the experiment showed that lecithin had an effect on the development of conditioned reflexes in rats:

(1) With a small dose, 1 mg/200 g BW, the conditioned reflexes of the test rats developed more quickly than with the controls, stabilized and were difficult to extinguish.

(2) With a large dose, 25 mg/200 g BW, a conditioned reflex which would make the rats run along the passage could not be developed.

C. Rabbits

In 1935, Downs (0720) reported the results of a study to examine the relation of fat metabolism to arteriosclerosis in young adult rabbits (no other specifications given). Groups of two rabbits each were fed a basic diet plus one of the following supplements daily: 0.25, 0.5, 1 or 2 g cholesterol; 3,6,12 or 18 grains pure lecithin; 2,4,6 or 8 minims Vitamin D concentrate (250D), or these elements combined in varying proportions.

It was observed that:

(1) At the higher feeding levels of lecithin animals "reacted strongly" and the feeding was discontinued after a few days.

(2) Groups receiving small doses of lecithin along with cholesterol and/or vitamin D did not develop vascular changes even where the cholesterol and D were administered in high doses over a four-month period.

The author concluded that the addition of small quantities of dietary lecithin will prevent experimental arteriosclerosis produced by high dietary cholesterol.

D. Dogs

In 1943, Davis (0632) studied the effect of daily administration of soybean lecithin to polycythemic dogs. The effect of oxygen as well as several other substances was also examined. Two dogs with cobalt polycythemia and three with pituitrin-induced polycythemia were given 3 g soybean lecithin p.o. daily.

The results are shown in Figure 3 . There were significant reductions in the erythrocyte counts of all five dogs with no appreciable change in leukocyte counts despite continuation of hemopoietic stimulating measures. Polycythemia returned to all dogs within about four days following cessation of lecithin administration. The authors concluded from their experimental results that depression of polycythemia was probably the result of an increase in oxygen supply to the bone marrow which diminishes local hypoxia, the probable stimulus to the development of polycythemia.

E. Babboons

In 1971, Howard et al. (1222) studied the effect of a polyunsaturated soya phosphatidyl choline (Lipostabil) on baboons made atherosclerotic by means of immunological injury.

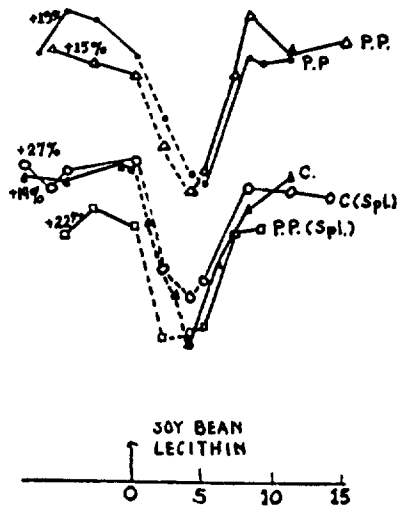


Figure 3 . Effect of Daily Oral Administration of 3 Grams of Soybean Lecithin on Experimental Polycythemia (0632)

P.P. = dog receiving posterior pituitary injections; C = cobalt fed dog

Male juvenile baboons (Papio cyanocephalus; 1-2 years old; about 4/kg) were given control laboratory pellets or a hypercholesterolemic diet. After 14 weeks they were either injected i.v. (femoral vein) with bovine serum albumin (BSA) and/or 10 ml containing 1 g Lipostabil. The experimental protocol was as follows:

Group 1: atherogenic diet, BSA every 16 days, saline thrice weekly.
Group 2: atherogenic diet, BSA every 16 days, Lipostabil thrice weekly.
Group 3: atherogenic diet, saline thrice weekly.
Group 4: control diet, BSA every 16 days, saline thrice weekly.
Group 5: control diet, no injections.

Only those groups given both atherogenic diets and BSA i.v. developed aortic and coronary atherosclerosis. The injection i.v. of 1 g polyunsaturated soybean phosphatidyl choline into these groups was found to:

(1) Reduce the incidence and severity of aortic atherosclerosis.
(2) Have no effect on plasma cholesterol phospholipids or the fatty acid composition of the cholesterol esters and lecithin.

F. Humans

In 1971, Tompkins (2805) reviewed the current knowledge of human gallstone formation. He noted that:

(1) Solubility of cholesterol in bile is about eight times greater mole per mole in lecithin solutions than in solutions of bile salts.

(2) Normal human subjects have a biliary phospholipid:cholesterol (P/C) ratio three times greater than that in persons having cholesterol gallstones.

(3) The P/C ratio of the author's patients was raised by addition of lecithin to a diet low in fat and cholesterol.

(4) Oral administration of lecithin to human subjects was well-tolerated and without complications.

The author concluded by pointing out the importance of discovering a non-toxic, easily tolerated method of increasing the cholesterol-dissolving capacity of human bile, such as that in feeding lecithin (see also Biological Data II, D, 4).

BIOCHEMICAL ASPECTS

I. Breakdown

Lecithin

Lysolecithin, a strongly hemolytic substance, was produced artificially in 1911 by the action of cobra venom on egg yolk. Subsequently, it was learned that the toxin resulted from the action of an enzyme in the venom, lecithinase A, which hydrolyzes off the beta fatty acid (usually unsaturated) of lecithin (1776, 2963).

McKillican (1776), in 1967, isolated lysolecithin from Thatcher wheat flour and concluded that the substance was primarily naturally occurring since it was present "in the original wheat endosperm extract before column separations were carried out". The author reported that other workers have found naturally occurring lysolecithins in animal tissues also (references in original article).

Ingleton (1256), in 1971, reported the presence of lysophosphatidyl ethanolamine and lysophosphatidyl serine as well as lysolecithin in commercial soyabean lecithin (see Table 2).

Fiori (0844) quoted Belfanti who detected free lysocithins in the pancreas and other organs (reference in original article).

In connection with the above-mentioned studies, West (2963) stated that lecithinase A occurs in various animal tissues; in the fresh organs it is held in check by other enzymes or substances but becomes active when the tissues are dried. Also, the higher fungi and other microorganisms produce lecithinase B; microbiological aspects were not mentioned in the above reports (2963).

Sartoretto (2441), 1967, stated that emulsions of lecithins like those used in the cosmetic, textile and leather industries may be decomposed by microorganisms if stored for protracted periods without preservatives.

Lecithins are susceptible also to breakdown by oxidation. Pure soybean phosphatides are unstable in air becoming dark in color and develop a disagreeable taste and odor (2441, 2806). The unsaturated fatty acids are reported to be the "focal point" of oxidation; iron salts catalyze the process (0915, 0168). Commercial soybean lecithins which contain soybean oil and natural antioxidants, however, are said to be stable for years under atmospheric conditions (0168, 2441).

Dahl and Josephson (0617) discovered that the oxidized off-flavor of whole milk powder was due to oxidation of lecithin in the fat globule membrane.

Lambert et al. (1552) found that aqueous solutions of soybean phosphatides as well as egg lecithin became spontaneously hemolytic and toxic for mice after storage at room temperatures for several months. Fat emulsions for injection which contained the lecithins as stabilizers also behaved in this manner.

Ashby (0155) reported that acetone-alcohol-ether purified egg lecithin exposed to air became toxic for rabbits (i.v.) after storage at room temperature for 47 days. The preparation which was originally amber in color became a dark red. At a storage temperature of 55°C, the material became toxic within 14 days. The freshly prepared material stored under high vacuum, on the other hand, remained non-toxic over 228 days.

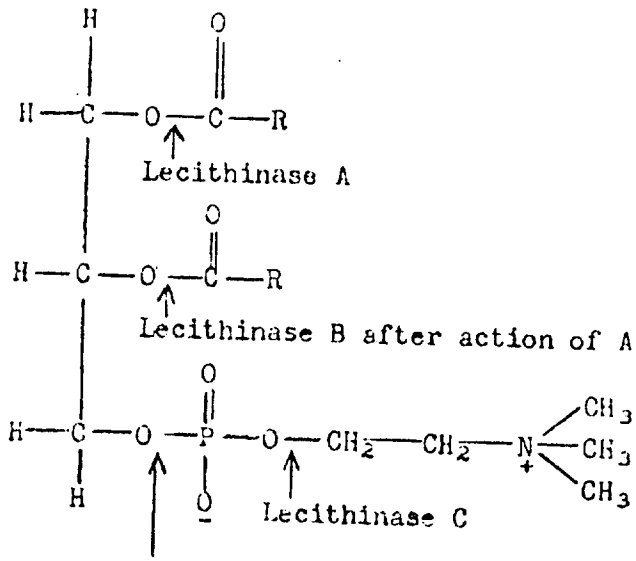
Lecithins are heat-labile and even mild heating may result in breakdown. Fiori (0844) found that prolonged warming of egg lecithin at 40° (2 months), aseptically and in the absence of air, caused decomposition with the formation of fatty acids and lysocithins. At 70°, the effect was greater. The author presented additional data which he claimed overrule contentions by other workers that his results were due to effects of lecithinase enzymes in the preparation (0845). (See original article for details).

Ingleton (1255), in 1971, reported that commercial lecithin is sensitive to heat and that only part of the recipe weight should be added during the early stages in confectionary and chocolate manufacture. Phosphatides break down after the temperature has exceeded 40°C (104°F) and high temperatures cause undesirable flavors (1255). The author stated that this is the main reason why a number of chocolate manufacturers are now using synthetic lecithins.

Sartoretto (2441) in 1967 pointed out that at 100°C lecithins are completely decomposed unless the heating period is very short. However, if the material is diluted with solvents such as glycerides and mineral oil, it is then stable for long periods of time above that temperature.

Lajara (1549) in 1970 warned that high temperatures used in the hydraulic pressing or expulsion methods of soybean lecithin manufacture tend to cause decomposition of the phosphatides. Ingleton (1256) in 1971 also stated that the amount of heat in commercial lecithin manufacture can affect its properties.

Lecithins can be hydrolyzed by four types of lecithinase enzymes designated lecithinase A, B, C, D, and phosphatase (1256, 2963). The points of attack are indicated in the following figure (1256). In some instances, toxic lecithins of



Lecithinase D, and phosphatase after choline and fatty acids have been removed. (1256)
Note: Some authorities (1776) claim that the beta ester linkage (linked at middle C atom) is the point of attack by lecithinase A.

the "lyso" type result (1256). Lecithinases are produced by bacteria and the higher fungi. The alpha toxin of Clostridium perfringens (Cl. welchii), the major gas gangrene microbe, for example is lecithinase D which splits off phosphocholine from lecithin in the cell membrane. As mentioned earlier, lecithinases are found in some animal organs but are normally held in check unless the tissues are dried out. Ansell et al. (0119) stated that "damage or bruising of plants can cause cell rupture and increased activity of lipolytic and/or oxidative enzymes. A major cause of off-flavor in many edible tissues is lipoxygenase which is involved in the production of odorous volatile carbonyl compounds from the polyunsaturated fatty acids of phospholipids and galacto lipids. Phospholipids in unblanched frozen peas are hydrolyzed even at -20°C. The deteriorative changes during storage of unprocessed foods are not easily prevented." However, blanching before freezing does destroy the enzymes (0119).

No specific reports were found on changes undergone by lecithins added to animal feeds or the products or metabolites resultant therefrom in the animal body. However, West (2963) listed a large number of products which "should be

obtained in the digestion of soy bean phosphatides". The toxic fatty acid, erucic acid, is a component of rapeseed phosphatides (See Soybean Oil monograph).

Hydrogen peroxide modified lecithin

No information.

Benzoyl peroxide modified lecithin

No information.

II. Absorption - Distribution

III. Metabolism and Excretion

IV. Effects on Enzymes and Other Biochemical Parameters

V. Drug Interactions

These sections are presented in tabular form. Relatively little information was found on the biochemistry of soybean lecithins taken by mouth. Reports on the endogenous lecithins of man and other animals were not considered pertinent to this monograph.

II. Absorption and Distribution

Animal	Findings and Conclusions	Year	Reference
Rats	Cottonseed oil (hydrogenated or not) was fed as 15% of diet. Addition of soy lecithin, 3% of diet, diminished diarrhea and accelerated absorption of the fats.	1947	0166
Rabbits, Rats	Addition of lecithin (source not stated) to diet tended to lower serum-free cholesterol, whether or not cholesterol was also fed.	1962	0722
Rats	Dietary lecithin was hydrolysed, absorbed as lyso-lecithin, reacylated, and then incorporated into lymph chylomicrons.	1967	2507
Rodent intestines *in vitro*	Lysolecithin was well absorbed and mostly converted to lecithin. There was "no definite evidence" that lecithin was absorbed intact.	1967	1978

III. Metabolism and Excretion

Animal	Findings and Conclusions	Year	Reference
Rats	Egg "lecithine" a choline prevented fatty liver, without increasing fat excretion.	1932	0266
Dogs	Egg lecithin by mouth was less calorigenic than neutral fat; given up to 1 g/kg i.v., it was not a calorie source. Conclusion: lecithin was not available to be oxidized, nor had it a role in fat metabolism.	1932	1041
In vitro	Animal lecithins were hydrolysed by a lecithinase present in kidney and gut preparations. Lysolecithin was hydrolysed more rapidly.	1934	1442
Dogs	Egg lecithin added to diet did not affect liver lipids.	1937	2384
Rats	Crude soy lecithin was "utilized to the extent of" 69.2%.	1944	1708
Rabbits	Alcohol-soluble soy-derived lecithin did not increase electrophoretic mobility of serum lipoproteins *in vitro*, when the alcohol-insoluble inositol phosphatide did so both *in vitro* and *in vivo*.	1958	2399
Rats	Egg lecithin intubated at about 250 mg/rat did not significantly alter plasma or tissue phospholipids 4 hours later, even though 96% was absorbed.	1966	1679
Human plasma *in vitro*	Lecithin:cholesterol acyltransferase acted on lecithin-rich lipoproteins to generate cholesterol esters. Liver influenced the reaction rate, but the *in vivo* significance remained undecided.	1968	0989

III. Metabolism and Excretion (Cont'd)

Animal	Findings and Conclusions	Year	Reference
Humans	From oral studies of synthetic, doubly-labeled lecithin, enterobiliary circulation of intact lecithin molecules was judged insignificant.	1970	2452
Rats	Lecithin infusions diminished the incorporation of ^{32}P into phospholipids of liver without affecting those of plasma.	1971	0432
Humans	Rate of lecithin excretion in bile was not related primarily to that of its excretion from liver; inferrably, lecithin was also synthesized in the biliary excretion pool.	1971	2469
Dogs	Conclusion: excretory transport of lecithin was coupled to that of cholesterol.	1972	2967
Pigs	Label from protozoan lecithin given i.v. appeared rapidly in bile, "probably" via intestinal breakdown products that reached liver by a route other than the thoracic duct.	1974	2806

IV. Effects on Enzymes and Other Biochemical Parameters

Animal	Findings and Conclusions	Year	Reference
Dogs	Lecithin from adrenals, given by mouth with or without high fat diet, constantly elevated the serum cholesterol.	1938	0583
Dogs	Choline, alone or in "purified" lecithin (source not stated) stimulated gastric secretion of fluid and acid weakly, and of pepsin more strongly.	1938	1686
Humans	Soy phospholipids (more cephalin than lecithin), 60 g by mouth, caused the respiratory quotient to fall and then rise excessively. Mainly this was an oxygen effect; the mechanism was not determined.	1939	2286
Rabbits	Soy lecithin in the diet diminished hypercholesterolemia and experimental atherosclerosis.	1942	1432
In vitro	Lecithin (Merck) was hemolytic in some systems, e.g. with oleic acid, and antihemolytic in others, e.g., with cholesterol.	1942	1579
Rats	Soy phosphatides and other substances helped rats to grow.	1943	2606
Rat, Rabbit, Dog, Cat	A soy phosphatide preparation for i.v. nutrition was vasodepressive in some species. The factor developed on contact with air, and fractions lacking it were unsatisfactory emulsifiers or were not stable.	1949	0968
Rats	Lecithin promoted absorption of fats, probably "by other than its emulsifying action."	1953	2787

IV. Effects on Enzymes and Other Biochemical Parameters (Cont'd)

Animal	Findings and Conclusions	Year	Reference
Humans	Soy lecithin, ca. 23 g/day for 90 days, p.o., to psychotics with cerebral arteriosclerosis, transiently lowered the serum low-density lipoproteins.	1958	0206
Rabbits	The anti-atheroma effects of two lecithins were related to the saturation or unsaturation of their fatty acids.	1967	0022
In vitro	Various synthetic lecithins and lysolecithins had different lytic effects on rbc. Recommended for experiments on mechanisms of hemolysis.	1967	2287
Dogs	Infusion i.v. of soy lecithin raised plasma insulin, so as to raise glucose absorption and lower plasma glucose.	1970	0587
Various species (review)	Conclusion: β-unsaturated lecithins, via action of lecithin: cholesterol acyltransferase, may contribute to esterification of cholesterol, and also may aid cholesterol transport via formation of water-soluble systems.	1974	1514

V. Drug Interactions

Drug	Animal	Findings and Conclusions	Year	Reference
Morphine	Rats	No interaction.	1934	1209
Dicumarol	Humans	Soy lecithin corrected the abnormal coagulation time and thrombin generation, but not the deficiency of thromboplastin generation.	1959	0362
DDT	*In vitro*	"A rather strong association" occurred, of the benzylic proton of DDT with the phosphorylcholine moiety of synthetic lecithin.	1971	2794
Deoxycorticosterone acetate (DCA)	Rats	Lecithin, source not stated, given "by any route", interfered with the hypertensive action of DCA.	1959	0897
Estrogen	Dogs	Soy lecithin 3 g/day in diet protected against toxicity from estrogen implants, but the toxicity was considered as possibly specific to dogs.	1947	3081
Vitamin A	Rats	Soy lecithin, but not its choline fraction, enhanced absorption and utilization of vitamin A and carotene.	1948	0802
Vitamin A	Cow	Soy lecithin imcreased the vitamin A transfer to milk. Vitamin A increased the transfer of added lecithin to milk. Lecithin increased absorption, liver storage, and utilization of vitamin A.	1948	0803
Vitamin A	Calves	"Vegetable" lecithin had "little" value for increasing absorption or utilization of supplementary vitamin A.	1956	0631
Vitamin A	Ewe, Sow	No significant or consistent effect of soy lecithin on absorption or utilization of vitamin A.	1949	0756
Vitamin A	Humans	Lecithin promoted absorption of A in sprue, but not in malabsorption of A due to severe liver damage.	1948	0035

VI. Consumer Exposure Information

Lecithin and Hydrogen Peroxide Modified Lecithin

Lecithins are extensively employed in the food industry for their antioxidant, emulsifying, dispersing, wetting, penetrating, and solubilizing properties (0563, 1132). Being edible, digestible, natural foods themselves, they have been considered to be especially applicable for the above-mentioned purposes in food processing (1305, 2673, 2677). The wide variety of foods in which they are used is indicated in the tables in this section.

In 1974, Krumdieck and Butterworth (1541) have pointed out that although lecithins are "being actively promoted and widely sold in health food stores, there have been no carefully controlled scientific evaluations of either their effectiveness or safety in statistically significant groups of humans." They suggest that the available evidence clearly justifies and indeed calls for, such studies." (See also Biochemical Aspects Section IV.)

A. NAS/NRC Survey Data

The estimated amount of lecithin in the average daily diet, maximum amount estimated in the daily diet, foods in which used at the maximum and the maximum use level, as reported in the Comprehensive GRAS survey are given in Tables 22 and 23.

Table 22. Estimated Amount of Lecithins in Average Daily Diet (0869).*

Additive	Number of Firms	Age Group	All Food Categories Possible Average Daily Intake mg
Lecithin	97	0-5 mo.	395.364100
		6-11 mo.	1306.064820
		12-23 mo.	1549.818140
		2-65+ yrs.	2034.276280
Lecithin, modified with Hydrogen Peroxide	7	0-5 mo.	15.510060
		6-11 mo.	136.233860
		12-23 mo.	231.547850
		2-65+ yrs.	512.942700

*From NAS/NRC Comprehensive GRAS Survey, Table 13, Part A, pages 93 and 242.

Table 23. Maximum Amount of Lecithins Estimated in the Daily Diet (0869) *

Additive	Number of Firms	Age Group	All Food Categories Possible High Daily Intake mg
Lecithin	97	0-5 mo.	779.772580
		6-11 mo.	5535.273640
		12-23 mo.	4485.726820
		2-65+ yrs.	5267.065930
Lecithin, modified	7	0-5 mo.	20.547040
		6-11 mo.	389.117860
		12-23 mo.	447.426260
		2-65+ yrs.	809.299690

*From NAS/NRC Comprehensive GRAS Survey, Table 13, Part A, pages 93 and 242.

According to the Comprehensive GRAS Survey reports (0867), lecithin is used at the maximum level in imitation dairy products (R), 1.89225%, wtd. mean. Hydrogen peroxide modified lecithin is used at the maximum level in baked goods (R), 0.44341%, wtd. mean. Other foods in which the latter is used near the maximum level are imitation dairy products (R), 0.39%, wtd. mean, and confectionary frostings (R), 0,38%, wtd mean.

The annual poundage data (1970) for lecithin and hydrogen peroxide modified lecithin, according to the Comprehensive GRAS Survey, are given in Table 24.

Comparative poundage data (1960 and 1970) for the two substances are given in Table 25.

Table 24. Annual Poundage Data for Lecithins (0871)*

Substance	No. Reports (1970) To NAS	To FEMA	Total 1970 Poundage NAS + FEMA
Lecithin	96	-	9,128,905
Lecithin Modified with Hydrogen Peroxide	7	-	403,078

*From NAS/NRC Comprehensive GRAS Survey, Table 11, Part A, pages 6 and 14.

Table 25. Comparative Annual Poundage Data for Lecithins (1960 & 1970) (0871)*

Substance	No. Reports to NAS 1960	No. Reports to NAS 1970	Poundage Reported to NAS (Matching Reports for Both Years) 1960	Poundage Reported to NAS (Matching Reports for Both Years) 1960	Poundage Reported to NAS (Matching Reports for Both Years) 1970
Lecithin	79	96	4,483,539		8,018,990
Lecithin Modified with Hydrogen Peroxide	4	7	97,585		228,048

*From NAS/NRC Comprehensive GRAS Survey, Table 11, Part A, pages 6 and 14.

See Comprehensive GRAS Survey tables 2, 3, and 13 (Part A) for amounts of lecithin and lecithin modified with hydrogen peroxide in the various food categories, and intake data related to age groups (0867, 0868, 0869).

B. FAO/WHO Intake Information

In 1964, the average diet provided a daily intake of approximately 1 to 5 grams of lecithin (1305).

The FAO/WHO estimate of acceptable daily intakes (ADI) for man, as of 1964, is given in Table 26.

Table 26. Estimate of Acceptable Daily Intakes for Man (1305)

Conditions	mg/kg BW (Additional to the daily intake in the usual diet)
Unconditional acceptance	0-50
Conditional acceptance	50-100

C. Reviews and Research Reports

The amount of "lecithin"[a] in cream and certain other dairy products, according to Heinemann (1144), varies as indicated in Tables 27 and 28.

The levels of lecithin used in processing a wide variety of food products and its effects on characteristics and quality are presented in Tables 29 and 30.

[a]Fat-like substances containing phosphorus extracted by the Mojonnier method.

Table 27. The "lecithin" Content of Cream of Varying Fat Percentage (1144)

Fat (Mojonnier), per cent	"Lecithin" in product, per cent	"Lecithin" in extracted fat, per cent
14.14	.066	.463
16.84	.077	.459
18.89	.089	.469
21.54	.087	.406
21.90	.081	.367
22.44	.084	.374
32.00	.112	.349
36.23	.124	.344
38.45	137	.358
38.48	126	.327
38.98	.146	.374
39.10	.145	.372
39.51	.138	.349
40.23	.156	.387
40.87	.156	.382
41.00	.154	.376
41.29	.152	.369
41.78	.160	.383
41.81	.151	.359
43.69	.156	.358
43.98	.164	.374
48.11	.153	.318
50.63	.163	.323
53.34	.165	.309
54.30	.162	.300
55.81	.187	.335
56.89	.179	.314
68.43	.211	.308
72.26	.196	.271
75.21	.210	.279
75.79	.194	.256
76.15	.199	.261

Table 28. The "lecithin" Content of Dairy Products (1144)

Product	Fat (Mojonnier), per cent	"Lecithin" in product, per cent	"Lecithin" in extracted fat, per cent
Skim milk	.075	.015	19.65
" "	.077	.018	24.05
" "	.066	.017	25.45
" "	.086	.017	19.79
" "	.080	.017	21.20
" "	.103	.017	16.55
" "	.077	.017	22.00
" "	.080	.016	19.97
" "	.089	.017	18.89
" "	.106	.016	14.78
" "	.096	.016	16.97
" "	.080	.018	21.90
" "	.090	.017	19.10
" "	.126	.018	14.52
" "	.076	.016	20.55
" "	.088	.016	18.42
Whole milk	5.01	.036	.720
" "	4.87	.035	.713
" "	5.50	.036	.655
" "	5.08	.036	.710
" "	5.10	.035	.691
" "	4.66	.035	.752
" "	4.71	.036	.765
" "	4.81	.035	.729
Sep. slime	1.12	.229	20.55
Buttermilk	.672	.114	16.93
"	.764	.128	16.81
"	.644	.126	19.55
Butter (sweet cream)	80.84	.216	.268
" " "	80.25	.209	.259
Butter (9 months in cold storage)	82.93	.165	.199
" " " " " "	82.69	.153	.184
Skim milk from 60–80% cream	.540	.093	17.25
" " " " "	.435	.084	19.36
" " " " "	.460	.080	17.40
" " " " "	1.378	.082	5.918
" " " " "	.196	.035	18.08
" " " " "	.192	.049	25.40

Table 29 Directions for Using Lecithin and Effects on Product Characteristics and Quality (0571)

ITEM	Quantity to use	Time of addition	Dough, batter, batch condition	Machinability or handling quality	Viscosity	Gloss	Texture	Grain	Color	Separation	Dispersion
1. Biscuits, hard cookies, ice box cookies	2% of fat	In mixer with fat or after flour cleared in	Drier, more pliable	Less sticky, clean mold or deposit		Slight	More tender		More uniform		Improved; checking reduced
2. Bread, rolls and sweet goods	2-3 oz. per 100 lb. flour	With shortening	Drier dough, more resilient	Less sticky			More silky crumb; more tender crust	More uniform	Of crust, more uniform		
3. Brittles	1% of fat	Direct to batch following fat					More tender			Retards separation	
4. Cakes (emulsified shortening)	1% of shortening	After obtaining full vol. in batter	More fluid	Cleaner deposit, lays flat in pans			More silky	More uniform	Of crust, more uniform		
5. Cakes (regular fats)	1-1¾% of shortening	After obtaining full vol. in batter	More fluid	Cleaner deposit, lays flat in pans			More silky	More uniform	Of crust, more uniform		
6. Caramels, nougats, toffees	1% fat	Direct to batch following fat		Less sticky			More tender, less sticky			Retards fat separation	
7. Chocolate	0.25-0.3%	Prior to tempering			Lowered	Improved					
8. Chocolate flavor for ice cream	0.25%	Prior to molding	Softer	Easier molding	Lowered						More rapid & complete in mix
9. Cookies (molasses)	4% of fat	In mixer with fat or after flour cleared in		Less sticky, clear cut		Slight	More tender	More uniform	More uniform		
10. Cookies (soft)	2% fat	In mixer with fat or after flour cleared in	More pliable	Clear cut, less sticky			More silky	More uniform	More uniform		
11. Doughnuts (cake type)	2% of fat	With fats		Clean deposit			Softer	More uniform	More uniform		
12. Doughnuts (raised)	2% of fat	With fats		Clean deposit			Softer		More uniform		
13. Dry mixes (various, prepared)	*(See individual products)*	With fats									Improved
14. Fat-bearing chocolate sirups and toppings	1% of fat	Premix in fat-containing constituents			Variable	Improved	Smoother			Retards fat separation	
15. Flavors (emulsions)	1-10% of oils	In oils		Rapid dispersion in product reduces flash evap. loss	Raised		Smoother			Reduced	More rapid in product; on consumer's taste buds
16. Flavors (oils)	1%	Unimportant		*(See above)*							*(See above)*
17. Gravies and sauces	1-2% of fats	Variable			Variable		Smoother			Reduced	
18. Hot chocolate and other powdered drinks	0.5-1.0% total dry weight	Before dehydration or before pulverizing or sifting									More rapid & complete in reconstitution
19. Ice creams (low solids) and sherbets	0.15%	Premixed with portion of sugar	Body less watery				Smoother	Less grit		Of air reduced	
20. Ice cream coatings	0.5%	Just prior to tempering			Lowered; maintained	Improved					
21. Icings and fillings of fat and suspended solids	1% of fat	Unimportant	Softer	More pliable	Lowered if no fat omitted	Improved	Smoother				
22. Icings of fat, moisture and solids	1% of fat	After obtaining full vol.	Softer	More pliable	Variable	Improved	Smoother				
23. Lard	0.1-0.25%	When under 150° F. and before Votating	Slightly softer							Slight improvement	More rapid and uniform
24. Meats (canned with gravy)	1-2% of fat	Variable					Gravy smoother			Of fat reduced	
25. Oleomargarine	0.1-0.75%	In fats		Reduces spattering					Slight tint with high %'s	Reduced weeping	More rapid and more uniform
26. Pan greases and slab grease (straight)	1% of fat	Before use			No change						More efficient coverage
27. Pan grease with suspended solids	1% of fat	When mixing	More fluid	Easier application	Lowered	Unimportant	Smoother			Slightly reduced	More efficient coverage
28. Peanut butter for commercial use	0.5%	After grinding	Softer	Easier deposit, bakg. reduced	Lowered	Unimportant	Smoother			Unimportant	Improved
29. Peanut butter for retail sale	0.5%	After grinding	Softer	Improved	Lowered	Slight	Smoother			Greater; correctable with solids	
30. Pie doughs	2% of fat	With shortening		Mixing time must be reduced			More flaky		More uniform		Fat in thinner layers
31. Shortening	0.25%	When under 150° F. and before Votating	Slightly softer								More rapid and uniform
32. Soda crackers	2-3 oz. per 100 lb. flour	With shortening	Drier dough	Less sticky			More tender	More uniform	More uniform		

ADDENDA: (1) Lecithin does not save fat except in items 7, 20 21, and 27. (2) It prolongs shelf life by inhibiting oxidation and by moisture retention. (3) It increases fermentation tolerance of 2 and 12.

Table 30. Some Applications of Lecithin in Food Processing

Food	Purpose	Levels Used	Reference
Margarine	Emulsifier; antioxidant (or synergist); stabilizer. Retards rancidity to vitamin A destruction; anti-spattering effect; prevents pan-sticking.	0.1-0.5%	0168 2674
Fats & Oils (edible)	Antioxidant Emulsifier	0.01-0.25% 1.0-5.0%	2674
Chocolate & chocolate coatings	Wetting agent; stabilizer. Reduces viscosity; prevents graying or bloom; reduces moisture absorption.	0.25-1.0%	2674
Confections	Emulsifier; antioxidant	1%[b]	2674,1172
Prep. break. cereal	Antioxidant	0.0025-0.005%	0870
Bread & cake	Emulsifier. Reduces shortening requirement; improves fermentation and texture; retards staleness.	0.1-0.5%[a]	2674
Biscuits, cookies, crackers	Same as above.	0.5-2.0%[b]	2674
Macaroni	Antioxidant. Prevents color loss; retards syneresis.	0.5%[c]	2674
Whole milk powder and infant formulas	Wetting and dispersing agent.	0.2%	0189
Dry milk powder	Wetting agent.	0.25%	2441
Dry malted-milk powder	Wetting agent.	1.0%	2441

Table 30. Some Applications of Lecithin in Food Processing (Cont'd)

Food	Purpose	Levels Used	Reference
Ice cream mix	Dispersing agent.	4 oz/100 lb	0572
Ice cream	Emulsifier	0.15%	2441
Frozen desserts	Emulsifier	up to 0.5%	0870

[a]on flour basis

[b]on fat basis

[c]in pre-mix

The Food and Drug Administration (0098) was petitioned in 1973 to permit the use of lecithin in pasteurized process cheese, cheese food, and cheese spread at a level of 0.03% maximum (by wt. of finished product) as an anti-sticking agent (slices and wrapper).

D. Regulatory Information

Lecithin is generally recognized as safe (GRAS) as a miscellaneous and/or general purpose food additive (0866).

The Meat Inspection Division permits the use of lecithin as an antioxidant and emulsifier in lard and shortening at a level sufficient for the purpose, and in oleomargarine as an emulsifier at a concentration of 0.5% (0866).

The use of lecithin is permitted also in the manufacture of paper and paperboard used in contact with foods and certain types of food container components as well as in coatings and resins (0866).

Benzoyl Peroxide modified lecithin

No information.

[¶ 55,927] Hydroxylated lecithin (0104)

§ 121.1027 The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, "hydroxylated lecithin."

(2) Adequate directions for its use.

Acceptable Daily Intake values for hydroxylated lecithin have not been defined according to a recent (1970) report of the Joint FAO/WHO Expert Committee on Food Additives (1306).

§ 121.1099 Defoaming agents may be safely used in processing foods, in accordance with the following conditions: (0103)

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this subparagraph, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200° C.; viscosity 300-600 centistokes at 25° C.; refractive index 1.400-1.404 at 25° C.).	10 parts per million in food, except zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready to serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
Polyethylene glycol	As defined in § 121.1185.
Polyoxyethylene 40 monostearate	As defined in U. S. P. XVI.
Polyoxyethylene (20) sorbitan monostearate.	As defined in § 121.1030.
Polyoxyethylene (20) sorbitan tristearate.	As defined in § 121.1008.
Propylene glycol alginate	As defined in § 121.1015.
Silicon dioxide	As defined in § 121.1058.
Sorbitan monostearate	As defined in § 121.1029.

(3) Substances listed in this subparagraph, provided they are components of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate	As defined in § 121.1071.
Butyl stearate	.....
BHA	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHT	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
Calcium stearate	As defined in § 121.1071.
Fatty acids	As defined in § 121.1070.
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in § 121.1027.

Substances	Limitations
Isopropyl alcohol	.....
Magnesium stearate	As defined in § 121.1071.
Mineral oil: Conforming with § 121.1146.	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.
Odorless light petroleum hydrocarbons: Conforming with § 121.1182.	
Petrolatum: Conforming with § 121.1166.	
Petroleum wax: Conforming with § 121.1156.	
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with § 121.1154.	
Oxystearin	As defined in § 121.1016.
Polyoxyethylene (600) dioleate	.....
Polyoxyethylene (600) monoricinoleate	.....
Polypropylene glycol	Molecular weight range, 1,200-2,500.
Polysorbate 80	As defined in § 121.1009.
Potassium stearate	As defined in § 121.1071.
Propylene glycol mono- and di-esters of fats and fatty acids.	As defined in § 121.1113.
Soybean oil fatty acids, hydroxylated	.....
Tallow, hydrogenated, oxidized or sulfated	.....
Tallow alcohol, hydrogenated	.....

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