Lecithin

1 Nonproprietary Names

USP–NF: Lecithin

See also Section 4.

2 Synonyms

Coatsome NC; E322; egg lecithin; *Epikuron*; *Lecigran*; *Lipoid*; mixed soybean phosphatides; ovolecithin; *Phosal 53 MCT*; *Phospholipon 100 H*; *ProKote LSC*; soybean lecithin; soybean phospholipids; *Sternfine*; *Sternpur*; *Topcithin*; vegetable lecithin; *Yelkin*.

3 Chemical Name and CAS Registry Number

Lecithin [8002-43-5]

The chemical nomenclature and CAS Registry numbering of lecithin is complex. The commercially available lecithin, used in cosmetics, pharmaceuticals, and food products, is a complex mixture of phospholipids and other materials. However, it may be referred to in some literature sources as 1,2-diacyl-*sn*-glycero-3-phosphocholine (trivial chemical name, phosphatidylcholine). This material is the principal constituent of egg lecithin and has the same CAS Registry Number. The name lecithin and the CAS Registry Number above are thus used to refer to both lecithin and phosphatidylcholine in some literature sources.

Another principal source of lecithin is from an extract of soybeans (CAS [8030-76-0]). Egg yolk lecithin (CAS [93685-90-6]) is also listed in *Chemical Abstracts*.

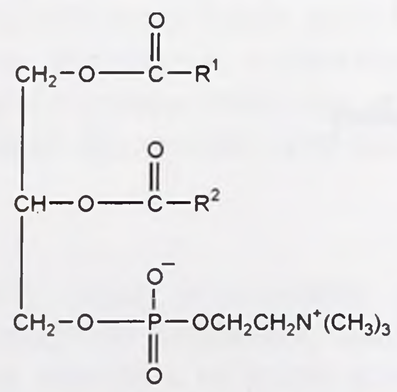
See also Section 4.

4 Empirical Formula and Molecular Weight

The USP 40–NF 35 S1 describes lecithin as a complex mixture of acetone-insoluble phosphatides that consists chiefly of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and phosphatidic acid, present in conjuction with various amounts of other substances such as triglycerides, fatty acids, and carbohydrates as separated from a crude vegetable oil source.

The composition of lecithin (and hence also its physical properties) varies enormously depending upon the source of the lecithin and the degree of purification. Egg lecithin, for example, contains 80.5% phosphatidylcholine and 11.7% phosphatidylethanolamine, along with lysophosphatidylcholine, sphingomyelin, and neutral lipids in minor quantities.[1] Soybean lecithin contains 21% phosphatidylcholine, 22% phosphatidylethanolamine, and 19% phosphatidylinositol, along with other components.[2]

5 Structural Formula



α-Phosphatidylcholine

R^1 and R^2 are fatty acids, which may be different or identical.

Lecithin is a complex mixture of materials; *see* Section 4. The structure above shows phosphatidylcholine, the principal component of egg lecithin, in its α-form. In the β-form, the phosphorus-containing group and the R^2 group exchange positions.

6 Functional Category

Emollient; emulsifying agent; solubilizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Lecithins are used in a wide variety of pharmaceutical applications; *see* Table I. They are also used in cosmetics[3] and food products.

Lecithins are mainly used in pharmaceutical products as dispersing, emulsifying, and stabilizing agents, and are included in intramuscular and intravenous injections, parenteral nutrition formulations, and topical products such as emulsions, creams, and ointments.

Lecithins are also used in suppository bases,[4] to reduce the brittleness of suppositories, and have been investigated for their absorption-enhancing properties in an intranasal insulin formulation.[5] Lecithins are also commonly used as a component of enteral and parenteral nutrition formulations.

Table I: Uses of lecithin.

Use	Concentration (%)
Aerosol inhalation	0.1
Biorelevant dissolution media	0.059–0.295
IM injection	0.3–2.3
Oral suspensions	0.25–10.0

8 Description

Lecithins vary greatly in their physical form, from viscous semiliquids to powders, depending upon the free fatty acid content. They may also vary in color from brown to light yellow, depending upon whether they are bleached or unbleached or on the degree of purity. When they are exposed to air, rapid oxidation occurs, also resulting in a dark yellow or brown color.

Lecithins have practically no odor. Those derived from vegetable sources have a bland or nutlike taste, similar to that of soybean oil.

9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

Table II: Pharmacopeial specifications for lecithin.

Test	USP 40–NF 35 S1
Identification	+
Water	≤2.0%
Lead	≤10 ppm
Heavy metals	≤20 ppm
Microbial contamination	
Aerobic microbial count	$\leq 10^3$ cfu/g
Yeasts and molds	$\leq 10^2$ cfu/g
Acid value	≤36
Peroxide value	≤10[a]
Hexane-insoluble matter	≤0.3%[b]
Acetone-insoluble matter	≥50.0%[c]
Phospholipids	+

(a) ≤3 if intended for use in injectable dosage forms.
(b) ≤1.0% for sunflower lecithin.
(c) ≥80.0% if intended for use in injectable dosage forms.