
Handbook of PHARMACEUTICAL EXCIPIENTS

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Lecithin

1. Nonproprietary Name

NF: Lecithin

2. Functional Categories

USP: Emulsifying and/or solubilizing agent.

Others: wetting and dispersing agent; emollient; digestible surfactant; moisturizer

3. Synonyms

Soybean phospholipids; mixed soybean phosphatides; soybean lecithin; vegetable lecithin; egg lecithin; ovollecithin.

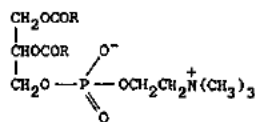
4. Chemical Name and CAS Registry Number

Phosphatidylcholine—commercially, a mixture of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, phytyglycolipids, other phosphatides, carbohydrates, triglycerides and other components. [8002-43-5]

5. Empirical Formula

Molecular Weight

6. Structural Formula



α -phosphatidylcholine

β -phosphatidylcholine

7. Commercial Availability

USA

American Lecithin
Central Soya Co.
Spencer-Kellogg

UK

Alembic (Lovelock) Products
Steetley Chemicals, Ltd.

8. Method of Manufacture

Crude soybean lipids are obtained by the solvent extraction of soybeans. Lecithin is obtained as a water extract of these crude soybean lipids. This crude lecithin is then upgraded by various techniques. Lecithin can also be made from corn, peanut, cottonseed, castor seed and coffee beans. It has been made from egg, known as egg lecithin. Synthetic lecithins are also made.

9. Description

Lecithin is brown to light yellow, depending on whether it is unbleached or bleached. It has practically no odor and a bland to nut-like taste, similar to soybean oil. In consistency, it may vary from plastic to fluid depending on the free fatty acid content.

10. Pharmacopeial Specifications

Test	NF
Water (method I)	$\leq 1.5\%$

Test

NF

Hexane-insoluble matter	$\leq 0.3\%$
Acetane-insoluble matter	$\leq 50.0\%$

11. Typical Properties

Isoelectric point: Approximately 3.5

Miscibility: When mixed with water, lecithin hydrates to form an emulsion. It readily forms imbibitions (taking up liquid without a measurable increase in volume) with almost any solvent.

pH: Approx. 6.6 (soybean phosphatides)

Solubility: Soluble in aliphatic and aromatic hydrocarbons, halogenated hydrocarbons, mineral oil and fatty acid. Insoluble in polar solvents and water. Practically insoluble in cold vegetable and animal oils.

Physical form: Liquid or granule (oil-free lecithin)

Density: Liquid lecithin, 0.97 g/cm³; granule lecithin, 0.5 g/cm³

Iodine value: Liquid lecithin, 95-100; granule lecithin, 82-88

Saponification value: 196

12. Stability and Storage Conditions

Fluid lecithin grades should be stored at room temperature or above (22°-49°C) in well-closed containers. Temperatures of 160-180°C will cause degradation within 24 hours. Temperatures below 10°C may cause separation. Lecithins are hygroscopic; keep containers closed to prevent moisture pickup. Lecithin is subject to microbial degradation. Exposure to light should be avoided. A shelf life of several years can be expected when stored at ambient temperatures.

13. Incompatibilities

Lecithin decomposes at extreme pH. When heated, it oxidizes, darkens and decomposes. It is hydrolyzed by esterases.

14. Safety

Lecithin is recognized as a multiple purpose food substance by the FDA.

15. Handling Precautions

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16. Regulatory Status

NF XVI

17. Applications in Pharmaceutical Formulation or Technology

Lecithins are used as dispersing and emulsifying agents for intramuscular injections. They are used in creams and ointments as dispersing, wetting, emulsifying and emollient agents.

18. Related Substances

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19. Comments

Since lecithin contains a variety of unspecified materials, care should be exercised in the use of unpurified lecithin in injectable or topical dosage forms, as interaction with the active ingredient or formulation excipients may occur.

20. Specific References

- P. Sartoretto, Lecithin. In "Encyclopedia of Chemical Technology," 2nd Ed., Kirk & Othmer eds., Vol. 12, John Wiley and Sons, Inc., 1967, New York, p. 343.