NATURAL HEALTH PRODUCT

PHOSPHATIDYLSERINE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

Date

February 27, 2026

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information			
		Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
Phosphatidylserine	Phosphatidylserine	N/A	*Helianthus annuus*	Seed	Isolate
		Phosphatidylserine-enriched soy lecithin	N/A	N/A	Synthetic
		Phosphatidylserine	N/A	N/A	Synthetic

References: Proper name: NIH 2024; Common name: NIH 2024; Source information: US FDA 2006; US FDA 2003.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-

based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

Helps support cognitive/brain health/function (Schreiber et al. 2000; Cenacchi et al.1993; Crook et al. 1992; Engel et al. 1992; Crook et al.1991; Maggioni et al. 1990).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

300 milligrams of Phosphatidylserine, per day (Schreiber et al. 2000; Cenacchi et al. 1993; Crook et al. 1992; Engel et al. 1992; Crook et al. 1991; Maggioni et al. 1990).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, Labelling of Natural Health Products for more details.

Product Facts
Medicinal ingredient in each capsule Phosphatidylserine XX mg
Uses • Helps support cognitive health.
Warnings
If applicable[1]: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**
Directions Adults 18 years and older: Take X capsule(s), X time(s) per day.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

[1]This section can be removed from the table if the product contains no allergen or aspartame.

References cited

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US FDA 2006: United States Food and Drug Administration. Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety: Agency Response Letter GRAS Notice No. GRN 000186. College Park (MD): Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety, US Food and Drug Administration; 2006. [Accessed 2025 January 16]. Available from: https://wayback.archive-it.org/7993/20171031031859/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154650.htm

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Version History

Publication date	Update type	Summary of main updates (from Feb 2026)
2026-02-27	Minor updates	• Introductory notes • Adjustment of the preparation information in Table 1 • Adjustment to the wording of the claim to match the cognitive function products monograph • Addition of notes in the Uses or purposes section • Risk statement wording • Inclusion of the standard statement for storage conditions • Inclusion of a Product Facts Table example • Reference section • Inclusion of version history information
2019-07-01	Validation	–
2009-09-04	Initial release	–