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Hydrogenated Soybean Oil

CAS RN®: 8016-70-4.

DEFINITION

Hydrogenated Soybean Oil is the product obtained by refining, bleaching, hydrogenation, and deodorization of oil obtained from seeds of the soya plant *Glycine max* Merr. (Fabaceae). The product consists mainly of triglycerides of palmitic and stearic acids.

IDENTIFICATION

- **A.** It meets the requirements in *Specific Tests* for *Fats and Fixed Oils, Fatty Acid Composition* ⟨401⟩.
- **B.** It meets the requirements in *Specific Tests* for *Melting Range or Temperature, Class II* ⟨741⟩.

IMPURITIES

- **Limit of Nickel**

Nickel standard solution: Immediately before use, prepare the equivalent of 0.2 µg/g of nickel by diluting 10 mL of nickel standard solution TS with water to 500 mL.

Sample solution: Weigh 5.0 g of Hydrogenated Soybean Oil into a previously tared platinum or silica crucible. Cautiously heat, and introduce into the substance a wick formed from twisted ashless filter paper. Ignite the wick. When the substance ignites, stop heating. After combustion, ignite in a muffle furnace at 600°. Continue the incineration until white ash is obtained. After cooling, transfer the residue, with the aid of two 2-mL portions of diluted hydrochloric acid, to a 25-mL volumetric flask, add 0.3 mL of nitric acid, and dilute with water to volume.

Standard solutions: Into three identical 10-mL volumetric flasks introduce 1.0, 2.0, and 4.0 mL of *Nickel standard solution*. To each flask add a 2.0-mL portion of the *Sample solution*, and dilute with water to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption, equipped with a graphite furnace

Analytical wavelength: 232.0 nm

Lamp: Nickel hollow-cathode

Analysis

Samples: *Sample solution* and *Standard solutions*

Determine the absorbances of the *Samples* at least three times each. Record the average of the steady readings for each of the *Samples*. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the added quantity of nickel, and draw the straight line best fitting the three plotted points. Extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Sample solution*.

Acceptance criteria: NMT 1 µg/g

- **Alkaline Impurities**

Sample: 2.0 g

Analysis: Dissolve the *Sample* by gently heating in a mixture of 1.5 mL of alcohol and 3.0 mL of toluene. Add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid VS to a yellow endpoint.

Acceptance criteria: NMT 0.4 mL of 0.01 N hydrochloric acid VS is required.

SPECIFIC TESTS

- **Melting Range or Temperature,** *Class II* ⟨741⟩**:** 66°–72°
- **Fats and Fixed Oils,** *Acid Value* ⟨401⟩

Sample: 10 g of Hydrogenated Soybean Oil

Analysis: Dissolve the *Sample* in 50 mL of a hot mixture of neutralized alcohol and toluene (1:1). Add 0.5 mL of phenolphthalein TS, and immediately titrate, while still hot, with 0.1 N potassium hydroxide VS to produce a permanent, faint pink color.

Acceptance criteria: NMT 0.5

• **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** Hydrogenated Soybean Oil exhibits the composition profile of fatty acids in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
<14	0	≤0.1
14	0	≤0.5
16	0	9–16
18	0	79–89
20	0	≤1.0
22	0	≤1.0
18	1	≤4.0
18	2	≤1.0
18	3	≤0.2

• **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩**:** NMT 5.0

• **Fats and Fixed Oils,** *Unsaponifiable Matter* ⟨401⟩

Sample: 5.0 g

Acceptance criteria: NMT 1.0%

• **Water Determination,** *Method I* ⟨921⟩**:** NMT 0.3%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. No storage requirements are specified.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROGENATED SOYBEAN OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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