Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-5023CF2C-9465-4CF2-AE02-24C61B341B44_1_en-US
DOI: https://doi.org/10.31003/USPNF_M44300_01_01
DOI Ref: f0ni0



# Lanolin

## DEFINITION

Lanolin is the purified, wax-like substance from the wool of sheep, *Ovis aries* L. (Fam. Bovidae), that has been cleaned, decolorized, and deodorized. It contains NMT 0.25% of water. It may contain NMT 0.02% of a suitable antioxidant.

## IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Chloride and Sulfate, *Chloride*⟨221⟩**

**Sample solution:** Boil 20 mL of alcohol with 1.0 g of Lanolin under a reflux condenser. Cool, add 1 mL of 2 N nitric acid, and filter. To the filtrate add 5 drops of a solution of 20 mg/mL of silver nitrate in alcohol.

**Blank:** Boil 20 mL of alcohol under a reflux condenser. Cool, add 1 mL of 2 N nitric acid, and filter. To the filtrate add 5 drops of a solution of 20 mg/mL of silver nitrate in alcohol. Ádd 0.50 mL of 0.020 N hydrochloric acid.

**Acceptance criteria:** 0.035%; any turbidity produced by the *Sample solution* does not exceed that produced by the *Blank*.

• **Foreign Substances**

Use pesticide-free grade reagents and solvents throughout this test. [Note—Reference materials of pesticides for use in the *Standard solution* may be obtained from any commercial source.[1]]

**Standard stock solutions:** Prepare stock solutions for each reference pesticide containing 100 mg/L in hexane. [Note—Concentrated stock solutions may be stored in glass-stoppered containers in a dark refrigerator at 2°–5° for up to 1 year. Most pesticides may be dissolved directly in hexane; however, the hexachlorocyclohexane isomers and the DDT group of pesticides may require initial dissolution in the minimum volume of acetone followed by dilution with hexane to the specified concentration.]

**Standard solution:** Dilute volumes of the *Standard stock solutions* quantitatively with hexane, and combine to obtain a composite *Standard solution* having the concentrations indicated in *Table 1*. Store the composite *Standard solution* in a glass-stoppered glass container in the dark at 2°–5°, and replace it every 2 months. [Note—Two or more separate composite *Standard solutions*, each preferably containing NMT 8 reference pesticides, may be prepared if needed. Reference pesticides should be selected for composite *Standard solutions* on the basis that relative retention times (see *Table 1*) differ sufficiently so that peaks in chromatograms will not be expected to overlap, and they should be selected and combined appropriately for the chromatographic system and detector used.]

**Table 1**

| Reference Pesticide[a] | Standard Solution (Concentration in µg/mL) | | Relative Retention Times (Relative to 1.0 for Chlorpyrifos) | |
|---|---|---|---|---|
| | Electron-Capture Detector | Flame-Photometric Detector | System I | System II |
| Tetrachloronitrobenzene (TCBN) | 0.05 | — | 0.29 | 0.24 |
| alpha-Hexachlorocyclohexane (alpha BHC) | 0.05 | — | 0.40 | 0.35 |
| beta-Hexachlorocyclohexane (beta BHC) | 0.30 | — | 0.43 | 0.56 |

| Reference Pesticide[a] | Standard Solution (Concentration in µg/mL) | | Relative Retention Times (Relative to 1.0 for Chlorpyrifos) | |
|---|---|---|---|---|
| | Electron-Capture Detector | Flame-Photometric Detector | System I | System II |
| Hexachlorobenzene (HCB) | 0.05 | — | 0.45 | 0.33 |
| gamma-Hexachlorocyclohexane (lindane) | 0.05 | — | 0.48 | 0.41 |
| Propetamphos | — | 0.30 | 0.48 | 0.42 |
| Diazinon | — | 0.20 | 0.52 | 0.40 |
| Dichlofenthion | 0.10 | 0.20 | 0.67 | 0.56 |
| Ronnel | 0.30 | 0.40 | 0.81 | 0.66 |
| Heptachlor | 0.10 | — | 0.83 | 0.60 |
| Malathion | — | 0.40 | 0.91 | 1.05 |
| Chlorpyrifos | 0.30 | 0.30 | 1.00 | 1.00 |
| Aldrin | 0.20 | — | 1.05 | 0.76 |
| Pirimiphos ethyl | — | 0.40 | 1.14 | 1.14 |
| Chlorfenvinphos Z | 0.40 | 0.40 | 1.17 | 1.40 |
| Heptachlor epoxide | 0.20 | — | 1.29 | 1.17 |
| Chlorfenvinphos E | 0.40 | 0.50 | 1.30 | 1.51 |
| Bromophos ethyl | 0.40 | 0.50 | 1.51 | 1.45 |
| 1,1'-Dichloro-2-(2-chlorophenyl)-2-(4-chlorophenyl)ethene (*o,pp*-DDE) | 0.30 | — | 1.55 | 1.51 |
| 1,1'-Dichloro-2-(4-chlorophenyl)-2-(4-chlorophenyl)ethene (*p,pp*-DDE) | 0.30 | — | 1.88 | 1.86 |
| Stirophos | 0.60 | 0.80 | 1.58 | 1.97 |
| alpha-Endosulfan | 0.40 | — | 1.63 | 1.47 |
| 1,1'-Dichloro-2-(2-chlorophenyl)-2-(4-chlorophenyl)ethane (*o,pp*-TDE) | 0.40 | — | 1.90 | 2.19 |

| Reference Pesticide[a] | Standard Solution (Concentration in µg/mL) | | Relative Retention Times (Relative to 1.0 for Chlorpyrifos) | |
|---|---|---|---|---|
| | Electron-Capture Detector | Flame-Photometric Detector | System I | System II |
| Dieldrin | 0.30 | — | 1.91 | 1.84 |
| Endrin | 0.40 | — | 2.13 | 2.29 |
| beta-Endosulfan | 0.40 | — | 2.19 | 2.77 |
| 1,1-Dichloro-2,2-bis(4-chlorophenyl)ethane (*p,pp*-TDE) | 0.40 | — | 2.41 | 2.87 |
| 1,1,1-Trichloro-2-(2-chlorophenyl)-2-(4-chlorophenyl)ethane (*o,pp*-DDT) | 0.40 | — | 2.55 | 2.70 |
| Ethion | 1.00 | 0.40 | 2.56 | 3.36 |
| Carbophenothion | 0.80 | 1.00 | 2.94 | 3.70 |
| 1,1,1-Trichloro-2,2-bix(4-chlorophenyl)ethane (*p,p'*-DDT) | 0.50 | — | 3.13 | 3.50 |
| Methoxychlor | 0.60 | — | 4.70 | 7.20 |
| Carbophenothion sulfone | 5.00 | — | 5.10 | 9.20 |
| Carbophenothion sulfoxide | 5.00 | — | 5.40 | 10.00 |

[a] Suitable materials may be obtained from either Chem Service, 660 Tower Lane, P.O. Box 3108, Westchester, PA 19381-3108 or Greyhound, 88 Grange Road West, Birkenhead, Merseyside, L43 4XF, England U.K.

**Gel permeation chromatography cleanup system**

**Eluant:** Methylene chloride and hexane (1:1)

**Column:** 25-mm × 50-cm; packed with a slurry of 35 g of styrene–divinylbenzene copolymer beads compressed to a bed length of about 20 cm

**Operating pressure:** 8–11 psi

**Flow rate:** 5 mL/min

Set up the chromatograph, adjusting to discard the fraction eluting from 0 to 12 min. Collect the fraction eluting from 12 to 32 min, and rinse for 2 min, discarding the rinse fraction.

**System suitability**

**Elution of lanolin:** Melt a suitable quantity of Lanolin, and pass through a fluted filter paper into a container. Transfer 6.0 g to a 50-mL volumetric flask. Dilute with *Eluant* to volume, and filter. Transfer 5.0 mL of this solution to the gel permeation chromatographic column, and elute with *Eluant*. Collect 100 mL of the column effluent in tared beakers in 10-mL increments. Evaporate the solvent, cool, weigh the beakers and contents, and calculate the amount of lanolin eluted in each 10-mL increment. The column is suitable if NLT 96% of the lanolin elutes in the first 60 mL.

**Elution of pesticide from lanolin:** Dissolve suitable quantities of diazinon, diclofenthion, bromophos ethyl, lindane, and dieldrin in hexane to obtain a *Standard solution* having concentrations of 0.4, 0.4, 1.0, 0.1, and 0.6 µg/mL, respectively. Transfer 5.0 mL of this solution to a 10-mL volumetric flask containing 1 g of USP Lanolin RS. Dilute with methylene chloride to volume. Transfer 5 mL of this solution to the gel permeation chromatographic column, and elute with 160 mL of *Eluant*. Discard the first 60-mL fraction, and collect the next 100-mL

fraction (from 60 to 160 mL). Transfer this collection fraction to a concentrator fitted with a graduated collection flask, add 50 mL of hexane, and concentrate by evaporation to 5 mL. Inject this fraction into the chromatographs described in *Chromatographic system I* and *Chromatographic system II*. Record the chromatograms, and measure the heights of the peaks obtained from the five pesticides in the *Standard solution*. Calculate the recoveries of each of the five pesticides used in the fortified USP Lanolin RS solution.

Prepare a test solution by mixing hexane with the *Standard solution* (1:1). Inject this into the chromatographs described in *Chromatographic system I* and *Chromatographic system II*. Record the chromatograms, and measure the peak heights of the five pesticides in the chromatogram of the *Sample solution*. Compare the peak heights from the fraction of the *Standard solution* to the peak heights of the corresponding pesticides from the *Sample solution*: NLT 85% of the added amounts of each of the five pesticides is recovered.

**Sample solution:** Transfer 6 g of Lanolin, previously melted to liquid form by heating on a hot water bath if necessary, to a 50-mL volumetric flask. Dissolve in 25 mL of *Eluant*, dilute with *Eluant* to volume, and filter. Transfer 5.0 mL of this solution to the column, and elute with 160 mL of *Eluant*. Discard the first 60-mL fraction, and collect the remaining fraction in a suitable evaporator. Concentrate by evaporation on a steam bath to 3 mL, add 50 mL of hexane, and evaporate again to remove all traces of methylene chloride, adjusting the volume with hexane to 3.0 mL.

**Chromatographic system I**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** GC

**Detector:** Electron capture

**Column:** 0.53-mm × 30-m fused silica capillary; bonded with a 1.5-µm layer of phase G1, and a 0.53-mm × 6-m fused silica uncoated guard column connected to a modified packed column-type injector system

**Column temperature:** 200°. [NOTE—The initial temperature of the column may be adjusted so that the retention times of ethion and *p,p'*-DDT are 2.56 and 3.1, respectively, relative to chlorpyrifos.]

**Carrier gas:** Helium

**Flow rate:** 25 mL/min. Adjust so that the retention time of chlorpyrifos is 4 min.

**Makeup gas:** Nitrogen, 40 mL per minute

**Injection volume:** 5 µL

**Chromatographic system II**

**Mode:** GC

**Detector:** Flame photometric

**Column:** 0.53-mm × 30-m fused silica capillary; bonded with a 1.0-µm layer of phase G3, and a 0.53-mm × 6-m fused silica uncoated guard column connected to a modified packed column-type injector system

**Column temperature:** 200°. [NOTE—The initial temperature of the column may be adjusted so that the retention time of ethion is 3.36 relative to that of chlorpyrifos.]

**Carrier gas:** Helium

**Flow rate:** 25 mL/min. Adjust so that the retention time of chlorpyrifos is 4 min.

**Makeup gas:** Nitrogen, 40 mL/min

**Injection volume:** 5 µL

**Analysis**

The following procedure is to be followed for *Chromatographic systems I* and *II*.

**Samples:** *Standard solution* and *Sample solution*

Calculate the quantity of the individual specified residue found in the sample taken:

$$\text{Result} = (r_U/r_S) \times (C/W) \times 30$$

$r_U$ = peak area of each residue from the *Sample solution*

$r_S$ = peak area of each residue from the *Standard solution*

$C$ = concentration of the reference pesticide in the *Standard solution* (mg/L)

$W$ = weight of Lanolin taken (g)

**Acceptance criteria**

**Individual specified residue:** NMT 10 ppm

**Total specified residue:** NMT 40 ppm

## SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE,** *Class II* ⟨741⟩

**Analysis:** Determine on a sample previously cooled to 8°–10°.

**Acceptance criteria:** 38°–44°

- **Fats and Fixed Oils,** *Acid Value (Free Fatty Acids)*⟨401⟩

**Sample:** 10.0 g

**Acceptance criteria:** The free acids obtained from the *Sample* require NMT 2.0 mL of 0.10 N sodium hydroxide for neutralization.

- **Fats and Fixed Oils,** *Iodine Value*⟨401⟩

**Sample:** 780–820 mg

**Acceptance criteria:** 18–36

- **Alkalinity**

**Sample:** 2.0 g

**Analysis:** Dissolve the *Sample* in 10 mL of ether, and add 2 drops of phenolphthalein TS.

**Acceptance criteria:** The liquid is not colored red.

- **Water-Soluble Acids and Alkalies**

**Sample:** 10.0 g

**Analysis:** Warm the *Sample* with 50 mL of water on a steam bath, constantly stirring the mixture until the Lanolin is melted.

**Acceptance criteria:** The fat separates completely on cooling, leaving the water layer nearly clear and neutral to litmus. Retain the water layer for the test for *Water-Soluble Oxidizable Substances* and *Ammonia*.

- **Water-Soluble Oxidizable Substances**

**Sample solution:** 10 mL of the solution from *Water-Soluble Acids and Alkalies*

**Analysis:** Add the *Sample solution* to 50 µL of 0.10 N potassium permanganate.

**Acceptance criteria:** The resulting solution does not completely decolorize within 10 min.

- **Ammonia**

**Sample solution:** 10 mL of the solution from *Water-Soluble Acids and Alkalies*

**Analysis:** Add 1 mL of 1 N sodium hydroxide to the *Sample solution*, and boil.

**Acceptance criteria:** The vapors do not turn red litmus to blue.

- **Water Determination,** *Method I*⟨921⟩

**Solution A:** Chloroform and methanol (3:2)

**Sample solution:** 250 mg/mL of Lanolin in *Solution A*

**Analysis:** Determine the water content of a 10.0-mL portion of the *Sample solution*. Perform a blank determination on 10.0 mL of *Solution A*, and make any necessary correction.

**Acceptance criteria:** NMT 0.25%

- **Petrolatum**

**Sample:** 3 g

**Analysis:** Heat the *Sample* on a steam bath, with frequent stirring, until its weight loss is NLT its water content. Boil 40 mL of dehydrated alcohol with 500 mg of the dried lanolin so obtained.

**Acceptance criteria:** The solution is clear or NMT opalescent.

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, preferably at controlled room temperature.
- **Labeling:** The label states that it is not to be used undiluted.
- **USP Reference Standards** ⟨11⟩

USP Lanolin RS

[1] Suitable materials may be obtained from either Chem Service, 660 Tower Lane, P.O. Box 3108, Westchester, PA 19381-3108 or Greyhound, 88 Grange Road West, Birkenhead, Merseyside, L43 4XF, England U.K.

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**Chromatographic Database Information:** Chromatographic Database

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Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID: GUID-5023CF2C-9465-4CF2-AE02-24C61B341B44_1_en-US**
**DOI: https://doi.org/10.31003/USPNF_M44300_01_01**
**DOI ref: f0ni0**