

**7723-ANHYDROUS LANOLIN****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Anhydrous lanolin

Bulk code: 7723

Internal code: 405486

**1.2 Synonyms.**

No information available.

**2. DESCRIPTION**

Appearance: Solid (wax).

Colour: Opaque yellow.

Odour: Characteristic.

Origin: Ovine.

**3. COMPOSITION/INFORMATION ON COMPONENTS**

CAS: 8006-54-0/128-37-0

EINECS: 232-348-6/204-881-4

INCI: Lanolin, 2,6 di-tert-butyl-p-cresol.

Composition: Combination of fatty alcohol and fatty acids, resulting from the refining of wool fat.

- Lanolin 99.98%
- BHT: 0.02%

**Method of production:** From wool fat obtained from the wool of live sheep, which are sheared every year for their well-being. The wool fat is bleached, rinsed and neutralised and finally distilled in the last step. It is made with hexane, and the content thereof at the end of the process of < 1 ppm.

The extreme purity of these grades is obtained through short-path distillation to remove pesticides and keep the free fatty alcohol content below 6%.

**4. PHYSICO-CHEMICAL DATA**

For more information, see the analysis report.

**Solubility:** It is soluble in chloroform, ether, acetone and benzene, slightly soluble in alcohol and practically insoluble in water, although it can absorb up to twice its weight without losing its consistency.

## 7723-ANHYDROUS LANOLIN

### 5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

### 6. DOSAGE

In cosmetics it is usually added between 1 and 10%.

However, it can be used as a pure ingredient (100%).

### 7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

#### **STORAGE**

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

#### **BSE/TSE:**

The wool fat is obtained strictly from wool sourced from countries that are free of any risk of BSE contamination (Australia, New Zealand, Argentina and Uruguay) and collected from healthy and live animals (exclusively farmed sheep).

These references are compliant with:

- Explanatory note EMA/410/Rev.3 of 5 March 2011 on minimising the risk of transmitting animal spongiform encephalopathy agents for human and veterinary medicinal products. The starting material used in its manufacture comes from animals from countries in which, according to the lists of the World Organisation for Animal Health (WOAH, formerly the Office International des Epizooties – OIE):
  - o No cattle born in the country in question have contracted BSE since 1990, and over the last five years (from the time the material was retrieved), scrapie has occurred with a frequency of no more than in isolated cases – according to the World Organisation for Animal Health (WOAH).

Our entry process conditions for raw materials are equivalent to those described in the regulation.

- Regulation 1069/2009 (Cat. 3).

**7723-ANHYDROUS LANOLIN****GMOs:**

The product does not contain GMOs.

**CMR substances:**

Based on the information on the raw materials, the production process and the equipment used, the product may contain trace levels of any of the following listed substances, which are technically unavoidable and a result of the manufacturing process: Hexane 290 ppm max. (ICH class 2 solvent) and its maximum in the final product is 14 ppm. This substance is classified as a CMR (carcinogen, mutagen and toxic for reproduction) substance according to EU Regulation 1272/2008/EC.

**SVHC:**

Due to the manufacturing process, the product does not contain any substances classified as a SVHC listed on the Candidate List for Authorisation updated in January 2020 by the ECHA.

**NANOPARTICLES:**

The product does not contain any nanoparticles based on the following definitions:

- EU Recommendation on the definition of nanomaterial No 2011/292/EC.
- EU Regulation No 1223/2009/EC on cosmetic products.
- French Decree No 2012-232 of 17 February 2012.

**VOCs:**

The product contains volatile organic compounds as defined in Swiss Ordinance 814.018 of 12 November 1997 on Incentive Tax: Maximum 290 ppm hexane according to CHMP / ICH /82260/2006 ICH Q3C (R8) Guideline on impurities: Residual solvents, their presence in the product being less than 14 ppm.

**IRRADIATION:**

The product has not undergone radiation or ionisation.

**RESIDUAL SOLVENTS:**

The following solvents are used in the manufacturing process and the presence of traces thereof is technically unavoidable, while respecting good manufacturing practices:

- Isopropyl alcohol (2-propanol, ICH Class 3, CAS 67-63-0): Maximum concentration generally found in the finished product: less than 200 ppm.
- Hexane (ICH Class 2, CAS 110-54-3): Maximum concentration generally found in the finished product: less than 14 ppm.

These concentrations are in accordance with Note for Guidance CHMP/ICH/82260/2006 ICH Q3C (R8) Guideline on impurities: Residual solvents.

**7723-ANHYDROUS LANOLIN****IMPURITIES:**

None of the substances listed below are used in the manufacturing process, nor are they intentionally added and are therefore not expected to be present (analysis of these substances is not performed):

Aflatoxins, Aluminium, Asbestos, Amines, Bisphenol, Parabens, Gluten, Lactose, Milk, Eggs, Latex, Glycol, Melamine, Glycol Ether, Formaldehyde, Palm/Palm Derivatives, Zinc Pyrithione.

Due to the manufacturing process, nitrosamines are not expected to be present. In line with EMA/511347/2019 Note for guidance, analyses are performed annually by an external laboratory.

**ELEMENTAL IMPURITIES:**

No metal catalysts are used in the manufacturing process.

ICH Q3D Directive (rev. 4, December 2014) concerning the presence of elemental impurities is not applicable to lanolin.

However, the product is tested annually in accordance with ICHQ3D and none of the heavy metals listed in Class 1 and Class 2A, i.e., Arsenic (As), Cobalt (Co), Cadmium (Cd), Nickel (Ni), Mercury (Hg), Vanadium (V) and Lead (Pb), have been detected.

In addition, none of the heavy metals listed in Class 2B and Class 3 are intentionally added.

**CALIFORNIA PROPOSITION 65:**

The product may contain the following substances listed in California Proposition 65 (<https://oehha.ca.gov/proposition-65/proposition-65-list>):

Hexane 290 ppm maximum (ICH class 2 solvent) and its level in the product is less than 14 ppm.

This product is technically unavoidable due to the manufacturing process.

**ALLERGENS:**

- **Food allergens:** Due to the manufacturing process, none of the allergens listed in Annex II to Regulation (EC) 1169/2011 are expected to be present, and moreover, they are not intentionally added during the manufacturing process.
- **Cosmetic allergens:** Due to the manufacturing process, none of the allergens listed in Annex III to Regulation (EC) 1223/2009 are expected to be present.

**HALAL:**

The product does not contain any animal derivatives other than wool fat/sheep wool (hair) sheared from live and healthy animals. Does not contain alcohol (ethanol) and the manufacturing process does not require the use of alcohol (ethanol).

It is our understanding that these references meet the requirements of the Halal standards, however the product is not certified.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

**TECHNICAL DATA SHEET**

Review date:

**14/12/2022**

Version:

**2.0**

## **7723-ANHYDROUS LANOLIN**

### **KOSHER:**

The product does not contain any animal derivatives other than wool fat/sheep wool (hair) sheared from live and healthy animals. Does not contain alcohol (ethanol) and the manufacturing process does not require the use of alcohol (ethanol).

It is our understanding that these references meet the requirements of the Kosher standards, however the product is not certified.

### **TESTED ON ANIMALS:**

The product has not been tested on animals for cosmetic purposes.

### **CITES:**

The product does not contain any of the ingredients listed in the appendices to these regulations.

### **ISO 16128:**

Natural Index = 0

Natural Origin Index = 0.98

### **REACH:**

Lanolin: Exempt from registration according to Annex V.

BHT: 01-2119565113-46-XXXX