

	Dossier technique et réglementaire / <i>technical and regulatory document</i> LANOLINE CODEX AD	Mars 2025 / March 2025
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INCI: Lanolin
N° CAS: 8006-54-0
N°EINECS/ELINCS: 232-348-6

DESCRIPTION / DESCRIPTION :

Esters d'acides gras et d'alcools gras obtenus par raffinage de la graisse de laine (stabilisé au BHT) / *Fatty acid and fatty alcohol esters, obtained by the refining of wool grease (stabilized with BHT)*

Matière première conforme à la Pharmacopée Européenne III^{ème} édition / *Raw material conforming to the European Pharmacopoeia 3rd edition*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Indice d'acide / <i>Acid value</i>	≤ 1 mg KOH / g	PE 2.5.1
Perte à la dessiccation / <i>Loss on drying</i>	≤ 0.5 %	PE 2.2.32
Point de fusion / <i>Melting point</i>	36 – 42 °C	PE 2.2.16
Point de goutte / <i>drop point</i>	38 – 44 °C	PE 2.2.17 (B)
Cendres / <i>ashes</i>	≤ 0.15 %	PE 2.4.14
Indice de saponification / <i>Saponification value</i>	90 – 105 mg KOH / g	PE 2.5.6
Indice d'iode / <i>Iodine value</i>	28 – 38 (Wijs)	PE 2.5.4
Indice de peroxyde / <i>Peroxide value</i>	≤ 20 meq O ₂ / kg	PE 2.5.5 (A)
Pouvoir d'absorption d'eau / <i>Absorption power of water</i>	≥ 200 %	-
Couleur à 80°C / <i>Color at 80°C</i> (GARDNER)	≤ 10	GARDNER
Teneur en BHT / <i>BHT content</i>	≤ 200 ppm	-

Ces éléments seront repris sur nos BA / *these elements will be on our CoA*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Non soluble dans l'eau. Soluble dans les solvants organiques tels que l'hexane et éther de pétrole / *Not soluble in water. Soluble in organic solvents such as hexane and petroleum ether*

Acidité / *Acidity* (FFA): max 0.5%

Teneur en chlorure max 150ppm

Paraffines / *paraffins*: max 1 %

APPLICATIONS :

Cosmétiques – Pharmaceutiques / *Cosmetics, pharmaceuticals*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Tonnelet ouverture totale de 50 kg / *full opening Keg of 50 kg*

Matière première non classifiée comme substance dangereuse / *Raw material not classified as a dangerous substance*

A conserver en emballage fermé, à l'abri de la chaleur, de la lumière et de l'humidité / *Store in closed package, protected from heat, light and moisture.*

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Additives	Contain BHT < 200ppm	
Allergen	Doesn't contain allergen listed in Regulation EC n° 1223/2009, and 2023/1545	
Animal Testing	Not tested on animals	
BSE - Bovine Spongiform Encephalopathy	Excluded from any risk of BSE in accordance with the explanatory note EMA/410/Rev.3 of the 5 of March 2011 and the Regulation EC 1069/2009 (Cat.3)	
California Prop 65	This product (CAS: 8006-54-0) is not listed	
Carcinogenic, Mutagenic and Reprotoxic (CMR)	Doesn't contain CMR (1272/2008 & 2023/1490)	
Composition	99.98% minimum of lanolin oil and 0.02% maximum of BHT as anti-oxydant	
Cosmetic	Complying with cosmetics Regulation n ° 1223/2009	
Cosmos / Ecocert	No data available	
Danger	This product is not classified as dangerous in accordance with CLP and ADR	
Dioxane	Doesn't contain Dioxane or 1.4 dioxine	
Ecolabel	No data available	
European Pharmacopoeia	This product is compliant to the 3 rd European Pharmacopoeia but not compliant with the current European Pharmacopoeia due to pesticide value	
Food	No data available	
Genetically Modified Organisms (GMO)	Doesn't contain OGM	
Inventories	Listed in China IECSC, Taiwan TCSI USA TSCA, Canada DSL,	Korea KECL, Thailand TECI Philippines PICCS, New Zealand NZIoC Australia AIIC
Geographic origin	Come from sheep raised in Australia, New Zealand, Argentina and Uruguay	
Glycol ether	Doesn't contain Glycol ether	
Halal	This product is Halal certified	
Heavy Metals	Doesn't contain heavy metals	
HS code	150500900	
Irradiation / ionization	This product has not been irradiated	
Kosher	This product is not Kosher certified	
Latex	Doesn't contain latex	
Manufacturing location	Belgium	
Microbiological data	Not expected – periodical tester for : -Pseudomonas aeruginosa / PCR, -Candida albicans / Ph.Eur, - Aerobic mesophilic micro-organism: ASU L00.00-88 2004-07, -staphylococcus aureus / PCR	
Microplastic	Doesn't contain microplastic (regulation 2023/2055)	
Nanomaterials	Doesn't contain nanomaterials (2011/696 & 1223/2009)	
Nutritional data	No data available	
Origin	100% animal sheep wool fat	
PAH/PFAS	Not expected	
Pesticide	Can contain pesticide max 40ppm	
Phthalate	Doesn't contain Phthalates	
Preservative	Contains BHT max 200ppm	

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Process	Woolgrease + hexan ↓ bleaching reactor ↓ rinsing column ↓ neutralization ↓ bleaching reactor ↓ 10-stage washing column ↓ distillation
REACH	Exempted from Registration REACH annex V
Residual Solvents	The following solvents are unavoidable during the manufacturing process: -Iso-propyric alcohol (2-propanol, class ICH3, cas 67-63-0), concentration in the finished product lower than 200 ppm -Hexane (class ICH 2, cas 110-54-3), concentration in the finished product lower than 14 ppm These concentrations are in conformity with the ICH guideline Q3C (R8)-residual solvents
RSPO	This product doesn't contain palm oil – Not concerned
Shelf Life	2 years
Substances of Very High Concern (SVHC)	Not expected in the product
Volatiles organic compounds (VOC)	Doesn't contain VOC (2010/79)

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The document annule et remplace tous documents techniques ou réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*