	Dossier technique et réglementaire / <i>technical and regularoty document</i> <b>LANOLINE CODEX AD</b>	Juillet 2018 / <i>July 2018</i>
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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 / *Esters of fatty acids and fatty alcohols obtained by refining of woolen fat*

Matière première conforme à la Pharmacopée Européenne III<sup>ème</sup> édition et américaine XXV<sup>ème</sup> édition / *Raw material conforming to the European Pharmacopoeia 3rd edition and American XXVth edition*

**CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Indice d'acide / <i>Acid value</i>	≤ 1 mg KOH / g	ST 01/00
Perte à la dessiccation / <i>Loss on drying</i>	≤ 0.5 %	ST 05/00
Point de fusion / <i>Melting point</i>	36 – 42 °C	ST 04/00
Point de goutte / <i>drop point</i>	38 – 44 °C	ST 04/00
Cendres / <i>ashes</i>	≤ 0.15 %	ST 08/00
Indice de saponification / <i>Saponification value</i>	90 – 105 mg KOH / g	ST 02/00
Indice d'iode / <i>Iodine value</i>	28 – 38 (Wijs)	ST 06/00
Indice de peroxyde / <i>Peroxide value</i>	≤ 20 meq O <sub>2</sub> / kg	PTLAB13
Chlorures / <i>Chlorides</i>	≤ 150 ppm	ST 09/00
Pouvoir d'absorption d'eau / <i>Absorption power of water</i>	≥ 200 %	ST 10/00
Couleur à 80°C / <i>Color at 80°C</i> (GARDNER)	≤ 10	GARDNER
Teneur en BHT* / <i>BHT content*</i>	≤ 200 ppm	CQ-009

\*Sans BHT à la demande / *\*Without BHT on demand*

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

**Ces caractéristiques sont conformes aux précédentes spécifications datées de Mai 2003 / *These features are in accordance with previous specifications dated on May 2003***

**CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:**

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

Masse volumique: 0.9 / *density: 0.9*


Acidité / *Acidity (FFA): max 0.5%*

Substances acides ou alcalines hydrolysables / *Hydrolyzable acidic or alkaline substances: Conforme / Compliant*

Substances oxydables hydrosolubles / *Water-soluble oxidizable substances: Conforme / Compliant*

Paraffines / *paraffins: max 1 %*

Matière première référencée au Japon : CLSC Part 4 : Anhydrous Lanolin / *Raw material referenced in Japan: CLSC Part 4: Anhydrous Lanolin*

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**APPLICATIONS :**

Cosmétiques – Pharmaceutiques / *Cosmetics, pharmaceuticals*


**CONDITIONNEMENT STANDARD / STANDARD PACKAGING :**

Tonnelet de 50 kg / *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.*

<b>Additives</b>	Doesn't contain acrylamide, amines, dioxin, formol or formaldehyde releasers, melamines, monomers, nitrosamines, ethylene oxide, sulfates, terpenes , aflatoxin, sulfate, terpenes, methylisothiazolinone
<b>Allergen</b>	Doesn't contain allergen listed in Annexes II et III of Regulation EC n° 1223/2009, doesn't contain gluten, lactose
<b>Animal Testing</b>	Has not been tested on animals in accordance with the amended European Cosmetic Directive 76/768/CE modified, since 2007, (evaluation of oral acute toxicity in rats - May 2007) as a result we confirm full compliance with the Regulation n° 1223/2009
<b>BSE - Bovine Spongiform Encephalopathy</b>	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)
<b>California Prop 65</b>	This product (CAS: 8006-54-0) is not listed
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	Doesn't contain CMR in accordance with Regulation 1223/2009 and Regulation CLP EC 1272/2008 and its modifications
<b>Composition</b>	99.98% minimum of lanolin oil and 0.02% maximum of BHT
<b>Cosmetic</b>	Are not part of the substances prohibited for the manufacture of cosmetic products listed in Annexes II and III of EC Regulation n° 1223/2009
<b>Cosmos / Ecocert</b>	<i>No data available</i>
<b>Danger</b>	This product is not classified as dangerous in accordance with CLP and ADR
<b>Dioxane</b>	Doesn't contain Dioxane
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopeia</b>	This product is not compliant with the European Pharmacopoeia
<b>Food</b>	<i>No data available</i>
<b>Genetically Modified Organisms (GMO)</b>	Doesn't contain OGM
<b>Inventories</b>	Europe REACH, Switzerland CH INV, Canada DSL, Australia AICS, Japan ENCS & ISHL, Korea KECI, Philippines PICCS, China IECSC, USA TSCA, New Zealand NZIoC
<b>Geographic origin</b>	Come exclusively from sheep raised in Australia, New Zealand, South America and South Africa
<b>Glycol ether</b>	Doesn't contain Glycol ether
<b>Halal</b>	This product is not Halal certified
<b>Heavy Metals</b>	Doesn't contain Al, As, Cd, Hg, Pb, Co, Ni, V in accordance with Directive ICH Q3D – Revision 4, relative on elementary impurities ( December 2014)
<b>HS code</b>	150500900
<b>Irradiation / ionization</b>	This product has not been irradiated
<b>Kosher</b>	This product is not Kosher certified
<b>Latex</b>	Doesn't contain latex
<b>Manufacturing location</b>	Belgium

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<b>Microbiological data</b>	Exempted from microbiological contamination: -Pseudomonas aeruginosa / PCR, -Candida albicans / Ph.Eur, - Aerobic mesophyllic micro-organism: ASU L00.00-88 2004-07, -staphylococcus aureus / PCR
<b>Nanomaterials</b>	Doesn't contain nanomaterials in accordance with Regulation EC n° 1223/2009
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	100% animal sheep wool fat
<b>Pesticide</b>	No control on the lanolin
<b>Phthalate</b>	Doesn't contain Phthalates
<b>Preservative</b>	BHT max 0.02%, doesn't contain paraben
<b>Process</b>	Woolgrease + hexan ->bleaching reactor -> rinsing column -> neutralization -> bleaching reactor -> 10-stage washing column -> distillation
<b>REACH</b>	Exempted from Registration REACH, this statement is part of the revision of Annex V of the Commission Regulation 987/2008 published on 8 October 2008
<b>Residual Solvents</b>	Do not contain any dangerous chemical substances, the following solvents are unavoidable during the manufacturing process: -Iso-propyric alcohol (2-propanol, class ICH3), concentration in the finished product lower than 5000 ppm -Hexane (class ICH 2), concentration in the finished product lower than 290 ppm These concentrations are in conformity with the ICH directive Q3C (revision 6)-residual solvents
<b>RSPO</b>	This product doesn't contain palm oil – Not concerned
<b>Shelf Life</b>	2 years minimum after manufacture
<b>Substances of Very High Concern (SVHC)</b>	Not expected in the product
<b>Volatiles organic compounds (VOC)</b>	Doesn't contain VOC

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