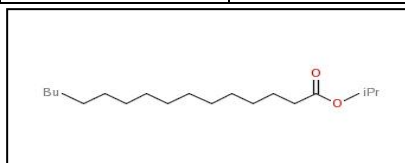


	Dossier technique et réglementaire / <i>Technical and regulatory document</i> <b>PALMITATE D'ISOPROPYLE</b>	Mai 2019 / <i>May 2019</i>
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INCI: **Isopropyl palmitate**  
N°CAS: 142-91-6  
N°EINECS/ELINCS: 205-571-1

**DESCRIPTION / DESCRIPTION:**

Ester de l'alcool isopropylique et de l'acide palmitique / *Ester of isopropyl alcohol and palmitic acid*  
Matière première conforme à la Pharmacopée Européenne en vigueur / *Raw material according to the European Pharmacopoeia in force*

**CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

CARACTERISTIQUES	SPECIFICATIONS
Indice de réfraction à 20°C / <i>Refractive index at 20°C</i>	1.436 – 1.440
Indice d'acide / <i>Acid value</i>	≤ 1 mg KOH /g
Indice de saponification / <i>Saponification value</i>	183 – 193 mg KOH /g
Indice d'iode / <i>Iodine value</i>	≤ 1 g I <sub>2</sub> / 100g
Teneur en eau / <i>Water content</i>	≤ 0.10 %
Viscosité à 20°C / <i>Viscosity at 20°C</i>	5 – 10 mPa.s

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

**Ces caractéristiques sont conformes aux précédentes spécifications datées de Mars 2010 / These features are in accordance with previous specifications dated on March 2010**

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

Couleur APHA / *Color APHA*: ≤ 70 (HAZEN)  
Densité à 20°C / *Density at 20°C*: 0.850 – 0.855 g/ml  
Essai / *Assay*:  
C 14 : ≤ 2 %  
C 16 : 98 – 100 %  
C 18 : ≤ 2 %  
Ce produit est végétalien / *This product is suitable for vegan*

**APPLICATIONS:**

Préparations cosmétiques / *Cosmetic preparations (emollient, skin conditioning, solvent)*


**CONDITIONNEMENT STANDARD / STANDARD PACKAGING:**

Tonnelet de 50 kg – Fût de 175 kg – IBC de 850kg/ *50kg keg – 175kg drum – 850kg IBC*  
A conserver à une température comprise entre 15 et 25°C. A conserver dans l'emballage d'origine à l'abri de la lumière du soleil, de l'humidité et des températures extrêmes / *Store at a temperature between 15 and 25°C. Keep closed in original packaging away from sunlight, moisture and extreme temperatures.*



**PALMITATE D'ISOPROPYLE**

<b>Additives</b>	<p>Additives as antioxidants, PAH, formol or fragrances are not added to this product during the manufacturing process, therefore these substances are not monitored analytically.</p> <p>A contamination with nitrosamines is not expected to be present.</p> <p>This product doesn't contain nitrosable or nitrosating substances as ingredients which allow a formation of nitrosamines, therefore these additives are not monitored analytically.</p> <p>This product is not monitored on aflatoxins. A presence of aflatoxins in the finished product is not expected to be present, with respect to the used raw materials and the production process</p> <p>This product is not classified as PBT or vPvB and doesn't contain any ingredients classified as PBT/vPvB according to regulation (EC) No.1907/2006</p>
<b>Allergen</b>	<p>Ingredients which are listed as allergens according to annex III (no. 67 – 92) regulation (EC) No.1223/2009 are not used for production of this product. Therefore, these ingredients are not monitored analytically.</p> <p>This product is not derived from any gluten containing cereals; the used raw materials do not represent a source for gluten; therefore, gluten is not monitored analytically.</p> <p>This product is not derived from nuts (allergen associated); traces of nut allergens are not monitored analytically</p>
<b>Animal Testing</b>	This product has not been tested on animals in terms of regulation (EC) No.1223/2009, Article 18
<b>BSE - Bovine Spongiform Encephalopathy</b>	This product is derived from vegetable and petrochemical/synthetical raw materials and does therefore not represent a source for BSE/TSE pathogens
<b>California Prop 65</b>	Substances listed in California Proposition 65 are not used as ingredients
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	This product is not rated as a CMR (category 1A, 1B, and 2) and doesn't contain any ingredients rated as CMR (category 1A, 1B, and 2) according to regulation (EC) No.1223/2009 in association with regulation (EC) No.1272/2008
<b>Composition</b>	>99 % isopropyl palmitate
<b>Cosmetic</b>	This product is not cited in annex II or III of regulation (EC) No.1223/2009, therefore the application in cosmetic preparations is not prohibited or restricted according to this regulation
<b>Cosmos / Ecocert</b>	This product is accepted with derogation by Ecocert natural and organic cosmetics by it contains petrochemical derivates – Not accepted by Cosmos
<b>Danger</b>	This product is not classified as dangerous in accordance to CLP and ADR
<b>Dioxane</b>	A contamination with 1, 4-dioxane is not expected to be present as the manufacturing process doesn't include an ethoxylation step. Therefore 1,4-dioxane is not monitored analytically
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopeia</b>	This product is compliant to the European Pharmacopeia
<b>Food</b>	Is not food grade product
<b>Genetically Modified Organisms (GMO)</b>	This product doesn't contain GMO and is not derived from a GMO. PCR analyses, to determine GMO traces are therefore not performed
<b>Inventories</b>	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI and NCSI, Philippines PICCS, Japan ENCS, Korea KECI, Australia AICS, Canada DSL
<b>Geographic origin (for plant)</b>	<i>No data available</i>
<b>Glycol ether</b>	Glycol ether are not added to this product during the manufacturing process. The process itself doesn't expect the formation of glycol ether, therefore this product is not monitored analytically
<b>Halal</b>	<i>No data available</i>

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<b>Heavy Metals</b>	Elemental impurities as listed in the “ICH guideline Q3D on elemental impurities” (EMA/CHMP/ICH/353369/2013) and in the Ph. Eur. General Text “5.20. Metal catalyst or metal reagent residues” are not intentionally added or used during the manufacturing process of this product. Therefore, it is unlikely that elemental impurities are present in this product in appreciable amounts. However, this product is analyzed on heavy metals including Cd, As, Pb, Hg, Ni, and Sb on a periodical basis. The sum of heavy metals, expressed as Pb, doesn't exceed 10 ppm
<b>HS code</b>	29157040
<b>Irradiation / ionization</b>	This product has not been treated with ionizing radiation during or after the manufacturing process
<b>Kosher</b>	<i>No data available</i>
<b>Latex</b>	<i>No data available</i>
<b>Manufacturing location</b>	<i>No data available</i>
<b>Microbiological data</b>	This product is not monitored on microbiological parameters. High processing temperatures and very low water content of the final product decrease the risk of microbial contamination
<b>Nanomaterials</b>	This product doesn't contain any ingredients classified as nanomaterials according to Commission Recommendation 2011/696 and regulation (EC) No. 1223/2009
<b>Nutritional data</b>	Not concerned
<b>Origin</b>	Palmitic acid is derived from vegetable (palm oil) Isopropanol is from petrochemical/synthetic origin
<b>Pesticide</b>	This product is not monitored on pesticides. A presence of pesticides in the finished product is not expected to be present, with respect to the used raw materials and the production process
<b>Phthalate</b>	Phthalates are not added to this product during the manufacturing process. The process itself doesn't expect the formation of phthalates, therefore this product is not monitored analytically
<b>Preservative</b>	Preservatives or antioxidants are not added to this product during the manufacturing process, therefore not monitored analytically
<b>Process</b>	Fatty acid (palmitic acid) + alcohol (isopropanol) → mixing → esterification → post treatment → packaging
<b>REACH</b>	This product is registered 01-2119541808-31
<b>Residual Solvents</b>	The class 3 solvent isopropanol is used as a starting material for the production of this product. The residue of this solvent is monitored with a threshold value of 50 ppm
<b>RSPO</b>	This product is derived from palm oil. This product is not certified RSPO. This same product is also available with RSPO-MB grade on <u>request only</u> . See our product “PALMITATE D'ISOPROPYL-RSPO-MB”
<b>Shelf Life before re-check</b>	2 years
<b>Substances of Very High Concern (SVHC)</b>	Substances cited in the current SVHC candidate list or already included in annex XIV of regulation (EC) No 1907/2006, are not used as ingredients
<b>Volatiles organic compounds (VOC)</b>	This product doesn't show a vapor pressure above or equal to 0.01 kPa at 20°C and needs therefore not to be classified as a VOC according to EU directive 1999/13 and Swiss VOCV

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