

	Dossier technique et réglementaire / <i>Technical and regulatory document</i> MYRISTATE D'ISOPROPYLE	Novembre 2019 / <i>November 2019</i>
---	--	--------------------------------------



INCI: Isopropyl myristate
N°CAS: 110-27-0
N°EINECS/ELINCS: 203-751-4

DESCRIPTION / DESCRIPTION :

Ester de l'alcool isopropylique et de l'acide myristique / *Ester of isopropyl alcohol and myristic 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
Pureté / <i>assay</i>	≥ 98%
Indice d'acide / <i>Acid value</i>	≤ 1 mg KOH /g
Indice de saponification / <i>Saponification value</i>	202-212 mg KOH /g
Indice d'iode / <i>Iodine value</i>	≤ 1 g I ₂ / 100g
Teneur en eau / <i>Water content</i>	≤ 0.10 %
Indice de réfraction à 20°C / <i>Refractive index at 20°C</i>	1.432 – 1.437
Viscosité à 20°C / <i>Viscosity at 20°C</i>	5 – 6 mPa.s
Couleur Apha	≤ 50
Cendre sulfurique / <i>sulfate ash</i>	≤ 0.1

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION :


Densité à 20°C / *Density at 20°C*: 0.846 – 0.855 g/ml
C 14 : ≤ 2 %
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 25/50 kg – Fût de 175 kg / *25/50kg keg – 175kg drum*
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.*

	Dossier technique et réglementaire / <i>Technical and regulatory document</i> MYRISTATE D'ISOPROPYLE	Novembre 2019 / <i>November 2019</i>
---	--	---

Additives	Additives are not added to this product during the manufacturing process, therefore these substances are not monitored analytically.
Allergen	<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>
Animal Testing	This product has not been tested on animals in terms of regulation (EC) No.1223/2009, Article 18
BSE - Bovine Spongiform Encephalopathy	This product is derived from vegetable and petrochemical/synthetical raw materials and does therefore not represent a source for BSE/TSE pathogens
California Prop 65	Substances listed in California Proposition 65 are not used as ingredients
Carcinogenic, Mutagenic and Reprotoxic (CMR)	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
Composition	> 99 % isopropyl myristate
Cosmetic	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
Cosmos / Ecocert	<p>This product is accepted with derogation by Ecocert natural and organic cosmetics.</p> <p>This product contains petrochemical derivates – Not accepted by Cosmos</p>
Danger	This product is not classified as dangerous in accordance to CLP and ADR
Dioxane	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
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product is compliant to the European Pharmacopeia
Food	Is not food grade product
Genetically Modified Organisms (GMO)	This product doesn't contain GMO and is not derived from a GMO. PCR analyses, to determine GMO traces are therefore not performed
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI and NCSI, Philippines PICCS, Japan ENCS, Korea KECI, Australia AICS, Canada DSL
Geographic origin (for plant)	South east Asia
Glycol ether	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
Halal	This product complies to halal requirements
Heavy Metals	<p>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.</p> <p>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</p>
HS code	2915907090
Irradiation / ionization	This product has not been treated with ionizing radiation during or after the manufacturing process
Kosher	This product is kosher certified

	Dossier technique et réglementaire / <i>Technical and regulatory document</i> MYRISTATE D'ISOPROPYLE	Novembre 2019 / <i>November 2019</i>
---	--	---

Latex	<i>No data available</i>
Manufacturing location	South east Asia
Microbiological data	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
Nanomaterials	This product doesn't contain any ingredients classified as nanomaterials according to Commission Recommendation 2011/696 and regulation (EC) No. 1223/2009
Nutritional data	For 100g : Energy 900Kcal, fat 0g, fat 100g which saturates 99g
Origin	~ 75-80% Myristic acid is derived from vegetable (palm oil) ~ 20-25% Isopropanol is from petrochemical/synthetic origin
Pesticide	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
Phthalate	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
Preservative	Preservatives are not added to this product during the manufacturing process, therefore not monitored analytically
Process	Fatty acid (myristic acid) + alcohol (isopropanol) → mixing → esterification → post treatment → packaging
REACH	This product is registered 01-2119541806-35
Residual Solvents	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
RSPO	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 "MYRISTATE D'ISOPROPYL-RSPO-MB"
Shelf Life before re-check	2 years
Substances of Very High Concern (SVHC)	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
Volatiles organic compounds (VOC)	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

----- END

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