	Dossier techn	ique et réglementaire / Technical and regulatory	Mai 2019 / May 2019
INTERCHIMIE	ΡΑ	document LMITATE D'ISOPROPYLE – RSPO – MB	
Bu O iPr		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 / Refractive index at 20°C	1.436 – 1.440
Indice d'acide / Acid value	≤ 1 mg KOH /g
Indice de saponification / Saponification value	183 – 193 mg KOH /g
Indice d'iode / Iodine value	≤ 1 g l₂/ 100g
Teneur en eau / Water content	≤ 0.10 %
Viscosité à 20°C / Viscosity at 20°C	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: \leq 70 (HAZEN) Densité à 20°C / Density at 20°C: 0.850 – 0.855 g/ml Essai / Assay: C 14 : \leq 2 % C 16 : 98 – 100 % C 18 : \leq 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.



Dossier technique et réglementaire / Technical and regulatory document

PALMITATE	D'ISOPROPYLE -	RSPO – MB
-----------	----------------	-----------

Additives	Additives as antioxidants, PAH, formol or fragrances are not added to this product
	during the manufacturing process, therefore these substances are not monitored
	analytically.
	A contamination with nitrosamines is not expected to be present.
	This product doesn't contain nitrosable or nitrosating substances as ingredients
	which allow a formation of nitrosamines, therefore these additives are not
	monitored analytically.
	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
	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
Allergen	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.
	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.
	This product is not derived from nuts (allergen associated); traces of nut allergens are
	not monitored analytically
Animal Testing	This product has not been tested on animals in terms of regulation (EC)
-	No.1223/2009, Article 18
BSE - Bovine Spongiform	This product is derived from vegetable and petrochemical/synthetical raw materials
Encephalopathy	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	This product is not rated as a CMR (category 1A, 1B, and 2) and doesn't contain any
and Reprotoxic (CMR)	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 palmitate
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	This product is accepted with derogation by Ecocert natural and organic cosmetics by
	it contains petrochemical derivates – Not accepted by Cosmos
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	No data available
European Pharmacopeia	This product is compliant to the European Pharmacopeia
Food	Is not food grade product
Genetically Modified	This product doesn't contain GMO and is not derived from a GMO. PCR analyses, to
Organisms (GMO)	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	No data available
plant)	
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	No data available
· · · · · · · ·	



Dossier technique et réglementaire / Technical and regulatory document

PALMITATE D'ISOPROPYLE – RS	PO – MB
-----------------------------	---------

Heavy Metals	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
HS code	29157040
Irradiation / ionization	This product has not been treated with ionizing radiation during or after the
	manufacturing process
Kosher	No data available
Latex	No data available
Manufacturing location	No data available
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	Not concerned
Origin	Palmitic acid is derived from vegetable (palm oil)
	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 or antioxidants are not added to this product during the manufacturing
	process, therefore not monitored analytically
Process	Fatty acid (palmitic acid) + alcohol (isopropanol) \rightarrow mixing \rightarrow esterification \rightarrow post
	treatment \rightarrow packaging
REACH	This product is registered 01-2119541808-31
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 RSPO-MB certified, see our certificate on our website
	www.interchimie.fr
Shelf Life before re-check	2 years
Substances of Very High	Substances cited in the current SVHC candidate list or already included in annex XIV
Concern (SVHC)	of regulation (EC) No 1907/2006, are not used as ingredients
Volatiles organic	This product doesn't show a vapor pressure above or equal to 0.01 kPa at 20°C and
compounds (VOC)	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.